William B. Federman
(admitted *pro hac vice*)
FEDERMAN & SHERWOOD
10205 N. Pennsylvania Avenue
Oklahoma City, OK 73120
Telephone: (405) 234-1560
wbf@federmanlaw.com

Lead Counsel for the Class

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

STEVEN MILLER, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. GALENA BIOPHARMA, INC., MARK J. AHN, MARK W. SCHWARTZ, RYAN M. DUNLAP, CHRISTOPHER S. LENTO, and REMY BERNARDA, Defendants.	Case No.: 2:17-cv-00929-KM-JBC FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS **JURY TRIAL DEMANDED**

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Lead Plaintiffs Dan Grunfeld, Shawn Kracht, Joseph Selinger, James Huisman, and Brooks Lieske ("Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and beliefs are based upon, among other things, Plaintiffs' counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Galena Biopharma, Inc., ("Galena" or the "Company"), with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Galena; (c) review and analysis of transcripts and exhibits from the criminal trial against Dr. Xiulu Ruan and Dr. John Patrick Couch in *USA v. Couch*, No. 1:15-cr-00088-CG-B (S.D. Ala.); (d) interviews with confidential witnesses, former employees of Galena; and (e) review of other publicly available information concerning Galena.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that acquired Galena's securities from August 11, 2014 through January 31, 2017, inclusive (the "Class Period"), against the Defendants,[1] seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Galena is a biopharmaceutical company that develops hematology and oncology therapeutics.

3. On March 18, 2013, Galena acquired its first commercial product, Abstral (fentanyl) Sublingual Tablets for sale and distribution in the United States from Orexo AB.

4. Abstral (fentanyl), a powerful opioid narcotic, is approved by the U.S. Food and Drug Administration ("FDA"), as a sublingual (under the tongue) tablet for the management of

[1] "Defendants" refers to Galena, Mark J. Ahn, Mark W. Schwartz, Ryan M. Dunlap, Christopher S. Lento, and Remy Bernarda collectively.

breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. Abstral is a transmucosal immediate release fentanyl ("TIRF") product with product class oversight by the TIRF Risk Evaluation and Mitigation Strategy (REMS) access program implemented by the FDA.

5. On October 3, 2013, the Company announced the product launch of Abstral (fentanyl). Galena manufactures and markets Abstral in the United States through its commercial organization. As explained by the Company in its SEC filings, Galena "sell[s] Abstral in the United States to wholesale pharmaceutical distributors and retail pharmacies, or our 'customers….'"

6. In July 2014, Galena acquired its second commercial product, Zuplenz (a nausea and vomiting treatment primarily used for persons on chemotherapy). Thus, during the Class Period, Galena had two commercial products that were approved by the FDA and could be marketed and sold: Abstral and Zuplenz. However, Galena had no sales of, or revenues from, Zuplenz during the Class Period or at any time, making Abstral Galena's only revenue generating commercial product.

7. Unbeknownst to investors, but known to Defendants, the Company's top two prescribers of Abstral were illegally prescribing the highly addictive medication throughout the Class Period. In May 2015, these prescribers were arrested for running a "pill mill" and their practices were shut down.

8. On August 6, 2015, Galena reported sales of $3.38 million from Abstral and an operating loss of $11.3 million for the second quarter ended March 31, 2015, underperforming Wall Street projections. Additionally, Galena announced that full-year revenue from the sale of Abstral, and the recently-launched Zuplenz (which generated no revenues during the Class Period), would be closer to $15 million, which was the low end of the Company's beginning-of-the-year forecast of $15 million to $18 million and about $1 million below what Wall Street was projecting.

9. On this news Galena's stock price fell $0.12, or 7.4%, from its closing price of $1.63 on August 6, 2015 to close at $1.51 on August 7, 2015.

10. Then, on November 9, 2015, Galena announced that it had decided to divest its commercial business, that is, Abstral and Zuplenz. As such, the Company's commercial business activities were classified as "discontinued operations," and Galena stated that it anticipated exiting the commercial business by the end of the first quarter of 2016. Galena also reported an $8.1 million impairment charge to its commercial business net asset group.

11. On this news, the price of Galena common stock fell $0.19 per share, or 11%, to close at $1.53 per share on November 10, 2015.

12. On November 20, 2015, the Company announced that it had sold its Abstral product to a private company in a deal valued at up to $12 million.

13. On December 11, 2015, the Company announced the departure of the Company's then Chief Financial Officer ("CFO"), Ryan Dunlap, effective December 31, 2015.

14. Then, on December 22, 2015, the Company announced that it received a subpoena from the U.S. Attorney's Office for the District of New Jersey requesting the production of a broad range of documents pertaining to marketing and promotional practices related to Abstral.

15. On this news, the price of Galena common stock fell $0.06 per share, or 3.6%, to close at $1.57 per share on December 23, 2015.

16. On March 10, 2016, the Company disclosed that "[a] federal investigation of two of the high-prescribing physicians for Abstral has resulted in the criminal prosecution of the two physicians for alleged violations of the federal False Claims Act and other federal statutes," and that the Company had received a trial subpoena in connection with that investigation and had been in contact with the U.S. Attorney's Office for the Southern District of Alabama, which was handling the criminal trial. The Company further stated that "other governmental agencies may be

investigating our Abstral promotion practices," and that "on December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office in District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral."

17. On this news, the price of Galena common stock fell $0.03 per share, or 3.3%, to close at $0.86 per share on March 11, 2016.

18. Then, on May 10, 2016, Galena announced that on April 28, 2016, a second superseding indictment was filed in the criminal case against the two doctors in Alabama, "***which*** added additional information about the defendant physicians and ***provided information regarding the facts and circumstances involving a rebate agreement between the Company and the defendant physicians' pharmacy as well as their ownership of our stock***" and that "we have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices."

19. On this news, Galena's stock price fell $0.10, or 7.2%, to close at $1.38 on May 11, 2016.

20. On January 9, 2017, the Company filed a Form 8-K with the SEC. Therein, the Company disclosed that the investigation being undertaken by the U.S. Attorney's Office for the District of New Jersey and Department of Justice was a criminal investigation in addition to a civil investigation that could ultimately involve the Company as well as one or more current and/or former employees, and that, pursuant to the Company's charter, it was reimbursing any former and current employees' attorney's fees with respect to the investigation.

21. On this news, the price of Galena common stock fell $0.04 per share, or 1.9%, to close at $2.03 per share on January 9, 2017.[2]

[2] The Company executed a 1-for-20 reverse stock split on November 11, 2016. All prices after that date in this complaint are the post-split prices.

22. The Class Period closes on January 31, 2017. On that date, the Company announced the resignation of Defendant Mark W. Schwartz as President, Chief Executive Officer ("CEO"), and a member of the Board of Directors and that the Company was "in the process of engaging an independent advisory firm to evaluate strategic alternatives for the company." News outlets tied Schwartz's abrupt resignation to the federal investigation of Galena's marketing and promotional practices for Abstral.

23. On this news, the price of Galena common stock fell $0.37 per share, or 22.4%, to close at $1.28 per share on February 1, 2017. The stock price continued to decline, falling another $0.16 per share, or 12.5%, to close at $1.12 on February 2, 2017.

24. Following the close of the Class Period, news concerning Galena's Abstral promotional practices, and the federal investigation of those promotional practices, continued to trickle out.

25. For example, on September 8, 2017, after the close of the Class Period, the United States Department of Justice ("DOJ") announced that it reached an agreement with Galena "to resolve allegations that [Galena] paid kickbacks to doctors to induce them to prescribe its fentanyl-based drug Abstral." The settlement resolves a lawsuit filed by a whistleblower under the False Claims Act, which permits private parties to file suit on behalf of the United States and obtain a portion of the government's recovery. As part of the settlement Galena agreed to pay $7.55 million. The DOJ press release stated: '"The conduct alleged by the government and resolved by today's settlement was egregious because it incentivized doctors to over-prescribe highly addictive opioids,' Acting U.S. Attorney Fitzpatrick said." No other information about the government's investigation of, or lawsuits against, Galena was disclosed due to the fact that "the matter remains under seal as to allegations against entities other than Galena."

26. Plaintiffs allege that during the Class Period, Defendants materially misled the investing public concerning the value of Galena's securities. Specifically, Defendants illegally promoted Abstral for off-label purposes (*i.e.*, non-cancer pain), paid illegal kickbacks to doctors that prescribed Abstral (including kickbacks for known off-label prescriptions), and encouraged and incentivized at least two doctors to illegally over-prescribe Abstral for non-legitimate medical purposes. These illegal and unsustainable practices artificially inflated Galena's revenues. Indeed, as Defendants knew, the Company's top two prescribers—who were responsible for 30% of all Abstral sales—were attempting to engage in a stock manipulation scheme to prop up the price of Galena's stock through outsized revenues generated by illegal over-prescriptions of Abstral, and then cash in once the prices were sufficiently high. In turn, Defendants used the outsized revenues to fund operations of the Company and used the overvalued stock to obtain equity financing.

27. Plaintiffs allege that Defendants made materially false and/or misleading statements and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose: (1) that Company's revenues were reliant on illegal and unsustainable practices, (2) that the Company violated various federal statutes in connection with its sales of Abstral; (3) that, as such, the Company's revenues were overstated and Galena was exposed to civil and criminal liability; and (4) that, as a result of these material omissions, Defendants' statements about Galena's business, operations, and prospects, were false and misleading.

28. As the concealed risks of Galena's illegal marketing and promotional practices materialized—*i.e.*, when the two over-prescribing doctors' practices were shut down and Abstral sales dropped off, and when the federal government opened investigations into Galena's Abstral promotional practices—and were revealed through a series of disclosures made by Galena, as set

forth above (and further herein), the artificial inflation in Galena stock dissipated and investors were damaged.

29. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

30. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

31. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

32. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

33. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

34. Plaintiff Dan Grunfeld, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and

suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

35. Plaintiff Shawn Kracht, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

36. Plaintiff Joseph Selinger, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

37. Plaintiff James Huisman, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

38. Plaintiff Brooks Lieske, as set forth in the certification previously filed with the Court, and incorporated by reference herein, purchased Galena common stock during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

39. Defendant Galena Biopharma, Inc. is a Delaware corporation headquartered in San Ramon, California. Galena's common stock trades on the NASDAQ Stock Market ("NASDAQ") under the symbol "GALE."

40. Defendant Mark J. Ahn ("Ahn") was the President, CEO, and a Director of Galena at all relevant times until his resignation effective August 20, 2014.

41. Defendant Mark W. Schwartz ("Schwartz") was the President, and CEO of Galena from August 20, 2014, through the end of the Class Period. From 2011 until his appointment as CEO, Schwartz served as Chief Operating Officer ("COO") for Galena.

42. Defendant Ryan M. Dunlap ("Dunlap") was the Vice President, and CFO of Galena from prior to the beginning of the Class Period until his resignation effective December 31, 2015.

43. Defendant Christopher S. Lento ("Lento") was the Senior Vice President of Oncology Commercial Operations at Galena from around May 2013 through December 31, 2015.

44. Defendant Remy Bernarda ("Bernarda") was the Senior Vice President of Investor Relations at Galena throughout the Class Period.

45. Defendants Ahn, Schwartz, Dunlap, Lento, and Bernarda (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of Galena's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers, and investors. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

IV. SUBSTANTIVE ALLEGATIONS

A. Background of Galena and Its Highly Addictive Drug, Abstral

46. Galena is a biopharmaceutical company that develops hematology and oncology therapeutics.

47. On October 3, 2013, the Company announced the product launch of Abstral (fentanyl) sublingual tablets, a drug designed to address breakthrough cancer pain. The Abstral formulation purportedly delivered micronized fentanyl in a convenient sublingual tablet which was designed to dissolve under the tongue in seconds and provide relief from breakthrough cancer pain within minutes.

48. Abstral (fentanyl) is an opioid pain medication that is associated with a high risk of addition and dependence. Fentanyl is reportedly fifty times more potent than heroin and up to 100 times stronger than morphine, making it the most powerful and potentially lethal opioid pain medication available. Like other opioids (including Oxycontin (oxycodone), Opana (oxymorphone), Dilaudid (hydromorphone), and Vicodin (hydrocodone)), fentanyl is highly addictive and is among the medications at the epicenter of the growing opioid epidemic in the United States, which has attracted the attention of United States regulators and other public officials, including former President Obama. In an October 21, 2015 Presidential Memorandum, entitled "Addressing Prescription Drug Abuse and Heroin Use," President Obama informed the heads of United States Executive Departments and Agencies, among other things, that:

> According to the Centers for Disease Control and Prevention (CDC), the number of overdose deaths involving prescription opioids quadrupled between 1999 and 2013, with more than 16,000 deaths in 2013. In recent years, overdose deaths involving heroin have sharply increased, nearly doubling between 2011 and 2013. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

49. On November 5, 2015, the U.S. Drug Enforcement Agency ("DEA") announced that drug overdose deaths had become the leading cause of injury death in the United States, ahead of deaths from motor vehicle accidents and firearms. On February 2, 2016, based upon the continuing widespread abuse of prescription opioids and resulting astronomical increase in heroin use nationally, President Obama proposed $1.1 billion in new funding "to address the prescription opioid

abuse and heroin use epidemic." The Fact Sheet announcing the President's budget proposal stated, among other things, that:

> New data from the Centers for Disease Control and Prevention (CDC) show that opioids—a class of drugs that include prescription pain medications and heroin—were involved in 28,648 deaths in 2014. In particular, CDC found a continued sharp increase in heroin-involved deaths and an emerging increase in deaths involving synthetic opioids, such as fentanyl.

50. Fentanyl is a major contributor to the alarming number of opioid overdose deaths currently plaguing the nation. For example, as reported in a May 14, 2016 Wall Street Journal article entitled "Hooked: One Family's Ordeal With Fentanyl," in twelve states particularly plagued by the opioid epidemic, including New Hampshire, Massachusetts, and Ohio, more than 5,500 people died of fentanyl-related overdoses between 2013 and 2015.

51. Abstral is specifically indicated by the FDA ***<u>only</u>*** for "the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Prescriptions written to patients that do not fit this criteria are considered off-label.

52. On March 3, 2014 Galena announced the launch of the Company's "Galena Patient Services (GPS)" to enhance access to Abstral by "guid[ing] the benefits investigation and prior authorization process," "help[ing] [to] manage the appeals and denials process," and "locat[ing] the preferred pharmacy." "'Patients suffering from breakthrough cancer pain are confronted with extraordinary issues on a daily basis, including insurance reimbursement and access,' said Mark J. Ahn, Ph.D., President and Chief Executive Officer. 'Galena Patient Services will offer support to these patients and their healthcare providers by managing the benefits approval process to make prescribing and receiving Abstral as simple as possible.'"

B. Legal and Regulatory Framework Governing Sales and Marketing of Abstral

1. FDA Regulations on Off-Label Marketing

53. Under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, 21 U.S.C. § 301, *et seq.*, a drug manufacturer, such as Galena, is prohibited from distributing drugs in interstate commerce for any intended use that the FDA has not approved as safe and effective. 21 U.S.C. § 355(a) and (b).

54. To obtain authorization from the FDA to sell a new drug product, a company must first submit and receive the FDA's approval of a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355. In the NDA, the company must describe all intended uses proposed for a new drug's labeling and prove that the new drug is safe and effective for those uses based upon data from its clinical trials. 21 U.S.C. § 355(b).

55. The FDA determines whether a medical product is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling submitted to the FDA with the product's marketing application or submission. In making this determination, the FDA evaluates whether the conditions of use in the proposed labeling are supported by the required levels and types of evidence of safety and effectiveness and whether the benefits of using the product under those specific conditions of use outweigh the risks of the product. After the FDA approves or clears a medical product, the FDA-required labeling sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing, and it provides directions and information on how to use the product safely and effectively under those conditions. *Guidance for Industry, (Draft Guidance), Medical Product Communication That Are Consistent With the FDA-Required Labeling – Questions and Answers*, at 2 (Background).

56. When the FDA reviews an NDA and approves a drug for commercialization, such approval is only with respect to the intended use(s) proposed in the NDA and approved for the drug's

labeling. In other words, "[a] use that does not appear in the labeling is not approved as safe and effective by FDA and is known as an 'unapproved' or 'off-label' use." 65 Fed. Reg. 14286-01.

57. When a company promotes an approved drug for an off-label use, the drug becomes an unapproved "new drug" with respect to that use. *See* 21 U.S.C. § 355(b), (d), (j). In addition, the approved drug is considered "misbranded" because the labeling of such a drug would not include "adequate directions for use" under 21 U.S.C. § 352(f). Both unapproved new drugs and misbranded drugs are prohibited from distribution in interstate commerce. *See* 21 U.S.C. 331(a), (d), (k). Accordingly, off-label marketing violates the FDCA.

58. The FDA-approved product label for Abstral states that the drug is "indicated for the management of breakthrough pain in ***<u>cancer</u>*** patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

59. While doctors are permitted to prescribe a pharmaceutical for a legitimate medical off-label purpose, it is illegal for drug companies to promote the off-label use of pharmaceuticals.

2. TIRF-REMS Access Program

60. As Abstral's black box warning advises, the drug is subject to the FDA-mandated TIRF-REMS Access Program, in which healthcare professionals who prescribe to outpatients, pharmacies, and distributors must be enrolled in order to obtain, prescribe, dispense, or distribute TIRF medications.

61. The purpose of the TIRF-REMS Access Program is to mitigate the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors with the use of the highly addictive and dangerous TIRF medicines. To this end, the TIRF-REMS Access Program implements various protocols designed to, among other things: (i) prescribe and dispense TIRF products only to appropriate patients, including only opioid-tolerant patients; (ii) prevent inappropriate conversion between fentanyl products; (iii) prevent accidental exposure to children and

others for whom TIRF products were not prescribed; and (iv) educate prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose.

3. Federal Anti-Kickback Provisions

62. In addition to FDA regulations, Galena's marketing practices are subject to federal anti-kickback laws, which prohibit, among other misconduct, offering, paying, or soliciting remuneration to induce the purchasing or ordering (or arranging for the purchase or ordering of) any healthcare item, such as a drug, reimbursable under any federally financed healthcare program, such as Medicare and Medicaid.

63. Specifically, under the Anti-Kickback Statute, it is illegal for an individual to knowingly and willfully offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program. *See* 42 U.S.C. § 1320a-7(b)(2). "Remuneration" refers broadly to anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program. *See* Department of Health and Human Services, Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003).

64. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thus interfering with the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 309 (proposed Jan. 23, 1989) (codified at 42 C.F.R. pt. 1001).

4. The Sunshine Act

65. Throughout the Class Period, Galena was required to comply with the Sunshine Act. As Galena disclosed in their filings with the SEC during the Class Period:

> The federal Patient Protection and Affordable Care Act include provisions known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 to the Centers for Medicare and Medicaid Services for subsequent public disclosures. ***Manufacturers must also disclose investment interest held by physicians and its family members.***
>
> [Emphasis added.]

C. Defendants Illegally Promoted Abstral and Utilized Disreputable Doctors to Artificially Inflate Abstral Sales and Revenues

1. Galena's Abstral Sales Were Propped Up By Two Doctors Illegally Prescribing Abstral

66. More than <u>***thirty percent***</u> of Galena's Abstral revenues were generated by just two pain management doctors, Dr. Xiulu Ruan and Dr. John Patrick Couch, who were convicted of running a pill mill in Mobile, Alabama.[3] At numerous times throughout the Class Period, Defendants Schwartz and Lento visited Dr. Ruan and Dr. Couch to encourage these doctors to prescribe Abstral to non-cancer patients. The facts alleged in the below paragraphs in this section came directly from information provided by the United States Department of Justice in public releases.

67. Dr. Ruan and Dr. Couch jointly owned and operated two pain management clinics under the name Physicians Pain Specialists of Alabama ("PPSA") as well as C&R Pharmacy, which was co-located with one of the PPSA clinic locations. C&R Pharmacy would only fill prescriptions written by the doctors at PPSA, and Dr. Ruan and Dr. Couch split 75% of the profits that came in from the prescription drug reimbursements. Accordingly to the DOJ, approximately 91% of the Abstral prescriptions written by Drs. Ruan and Couch—which cost their patients' insurance anywhere between $1,000.00 to $24,000.00 per month—were filled at C&R Pharmacy.

68. PPSA's clinics were raided by law enforcement on May 20, 2015, following an extensive joint investigation by the FBI and DEA. Both doctors were charged with a litany of federal

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[3] Another 10% was generated by Dr. Rho, also a pain management doctor and a "good friend" of Dr. Ruan.

felony offenses, including RICO conspiracy, conspiracy to violate the Controlled Substances Act, substantive drug distribution offenses, conspiracies to commit wire fraud, mail fraud, healthcare fraud, and to violate the federal Anti-Kickback Statute, as well as money laundering. All charges stemmed from the doctors' operation of PPSA and C&R Pharmacy.

69. During a seven week trial, which lasted from early January to late February 2017, the United States presented evidence that Dr. Ruan and Dr. Couch utilized PPSA and C&R Pharmacy as a criminal enterprise to violate the Controlled Substances Act and to commit mail and wire fraud, in violation of the RICO Act. Specifically, the government presented evidence that Drs. Ruan and Couch knowingly and willfully prescribed Schedule II and III Controlled Substances, including fentanyl, outside the usual course of professional practice and not for a legitimate medical purpose. The government also presented evidence that Drs. Ruan and Couch conspired to commit healthcare fraud. The United States argued Drs. Ruan and Couch's motives for this illegal prescribing were their own financial self-interests.

70. Of particular importance in the trial were two brand name instant-release fentanyl drugs — Abstral and Subsys. Both Abstral and Subsys are only FDA-indicated for breakthrough cancer pain in opioid-tolerant adult patients. However, evidence showed that Dr. Ruan and Dr. Couch almost exclusively prescribed these drugs off-label for neck, back, and joint pain.

71. With regard to Abstral, evidence showed that Dr. Ruan and Dr. Couch purchased more than $1.6 million worth of stock in Galena, the manufacturer of Abstral, and sought to manipulate the stock price by driving up Abstral sales. From the third quarter of 2013 through at least the end of 2014, Dr. Ruan and Dr. Couch were the number one and two prescribers of Abstral in the entire United States. During this same time period, ***nearly one out of every three*** Abstral prescriptions written in the U.S. were written by either Dr. Ruan or Dr. Couch. The jury also found that Dr. Ruan and Dr. Couch received illegal kickbacks from Insys Therapeutics, the manufacturer

of Subsys, in exchange for the defendants prescribing massive quantities of that drug. Dr. Ruan and Dr. Couch were both among the top prescribers of Subsys in the entire United States.

72. After seven weeks of trial, 81 witnesses, and three days of deliberation, the jury reached the following verdicts: Both doctors were convicted of (1) RICO conspiracy; (2) Conspiracy to prescribe Schedule II and III Controlled Substances outside the usual course of professional practice; (3) Conspiracy to prescribe more than 40 grams of fentanyl outside the usual course of professional practice; (4) Conspiracy to commit healthcare fraud; (5) Conspiracy to commit mail and wire fraud; (6) Conspiracy to receive illegal kickbacks from IPM/CRX related to the workers compensation dispensary; and (7) Conspiracy to receive illegal kickbacks from Insys Therapeutics in exchange for prescribing Subsys. In addition, Dr. Ruan was convicted of both conspiracy and substantive money laundering counts. Each doctor was also convicted of several substantive illegal drug distribution counts related to prescriptions written to particular patients. Dr. Ruan was acquitted of one substantive charge related to prescriptions written for a patient.

73. Subsequently, the DOJ instituted a civil and criminal investigation into Galena for illegal kickbacks Galena paid to doctors, including Drs. Ruan and Couch, in violation of the Anti-Kickback Statute and False Claims Act. As disclosed in a press release issued by the DOJ on September 8, 2017, the action was settled in exchange for Galena paying more than $7.55 million to the government. The DOJ's September 8, 2017 press release read, in pertinent part, as follows:

> Galena Biopharma Inc. (Galena) will pay more than $7.55 million to resolve allegations under the civil False Claims Act that ***it paid kickbacks to doctors to induce them to prescribe its fentanyl-based drug Abstral***, the Department of Justice announced today.
>
> "Given the dangers associated with opioids such as Abstral, it is imperative that prescriptions be based on a patient's medical need rather than a doctor's financial interests," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "The Department of Justice intends to vigorously pursue those who offer and receive illegal inducements that undermine the integrity of government health care programs."

"The conduct alleged by the government and resolved by today's settlement was egregious because it incentivized doctors to over-prescribe highly addictive opioids," said Acting U.S. Attorney William E. Fitzpatrick for the District of New Jersey. "This settlement constitutes another example of the Department of Justice's ongoing efforts to battle the opioid epidemic on every front."

The United States contends that Galena paid multiple types of kickbacks to induce doctors to prescribe Abstral, including providing more than 85 free meals to doctors and staff from a single, high-prescribing practice; paying doctors $5,000, and speakers $6,000, plus expenses, to attend an "advisory board" that was partly planned, and attended, by Galena sales team members and paying approximately $92,000 to a physician-owned pharmacy under a performance-based rebate agreement to induce the owners to prescribe Abstral. The United States also contends that Galena paid doctors to refer patients to the company's RELIEF patient registry study, which was nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral. Galena has not marketed any pharmaceutical drug since the end of 2015.

Two of the doctors who received remuneration from Galena were tried, convicted and later sentenced to prison in the U.S. District Court for the Southern District of Alabama following a jury trial of, among other counts, offenses relating to their prescriptions of Abstral. Galena cooperated in that prosecution.

***

The settlement is the result of a coordinated effort by the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the District of New Jersey, with assistance from the Department of Health and Human Services Office of Counsel to the Inspector General, and the Food and Drug Administration Office of Criminal Investigations' Metro Washington Field Office.

[Emphasis added.]

74. The DOJ also brought charges against former officers of Insys Therapeutics, Inc., the manufacturer of Subsys, for illegal kickbacks the company paid to doctors in exchange for writing prescriptions of Subsys.

2. Galena's Undisclosed Illegal Marketing and Promotion of Abstral

75. During the Class Period, Galena and Defendants marketed Abstral for off-label purposes and encouraged Drs. Ruan and Couch, along with other non-cancer pain management doctors, to prescribe Abstral to non-cancer patients.

a. Confidential Witnesses

76. According to Confidential Witness 1 ("CW1"), a Territory Business Manager at Galena from August 2013 through December 2014, Galena pushed its salespeople to market Abstral to pain specialists the entire time he worked at the Company. "I was always pushed to see doctors who didn't see any cancer patients," CW1 said. CW1 explained that because Galena "couldn't get enough revenue from on-label patients," Galena encouraged its sales force to market Abstral to pain management doctors who did not treat cancer patients and that this amounted to off-label promoting by Galena. CW1 explained that "I felt very strongly about promoting on-label. I was very uncomfortable with the fact that more and more business was being generated by pain specialists." According to CW1, Galena's management said "'Hey look – that's where you can get more business.'" CW1 explained that Galena's sales force "didn't have the relationships" in the oncology field to sell to cancer doctors. CW1 said he/she was let go from the Company in December of 2014 after CW1 told his/her manager he/she was uncomfortable with the Company's focus on off-label marketing. ***CW1 said that Galena's sales records would reflect that "the top prescribers were pain specialists. If you go in their offices you never see any cancer patients and I think that's horrible."***

77. Confidential Witness 2 ("CW2") was a Territory Business manager at Galena from April 2014 until April 2015 when CW2 was let go for failing to meet his/her sales quotas. CW2 worked in Ohio, Indiana and Kentucky and reported to Regional Manager Scott Makenzie, who reported to David Corin (Galena's National Director of Sales), who in turn reported to Defendant Lento. According to CW2, Galena had difficulties selling Abstral to oncologists because they did not have many pain patients. Similarly, hospices would not prescribe Abstral because it was too expensive. CW2 explained that pain clinics did not have many cancer patients, which is who the drug was intended for. CW2 said he/she could not make Galena's monthly sales quota because there were "not many real patients" for Abstral. "If you're selling ethically you can't do it," CW2 said.

78. Confidential Witness 3 ("CW3") was a Territory Business Manager for Galena from August 2014 through August 2015. CW3 reported to the Regional Sales Manager (Michael Hemenway and then Danielle Goodin), who reported to David Corin (Galena's National Sales Director), who in turn reported to Defendant Lento (Senior VP of Oncology Commercial Operations). CW3 described that Galena was pushing its sales staff to market to non-cancer prescribers, such as pain clinics and primary care doctors. CW3 said he/she felt that Galena wanted its sales representatives to "chase back pain prescriptions or amputee prescriptions." CW3 explained that most of Galena's sales team had no oncology drug sales experience but instead had backgrounds in selling pain management drugs or generic drugs.

79. CW3 provided a February 5, 2015 email from David Corin (Galena's National Sales Director), which ***copied Defendant Lento***. In the email, Mr. Corin wrote to his Abstral sales team, in relevant part, the following:

> It's no mystery to anyone that January was significantly lighter than December. Now, armed with the data, my hope is that we get back in front of these customers and turn the momentum in your favor. Here's what's in the attached file:
>
> 1. Tab 1- An overall running monthly summary of every Abstral prescriber from Day 1…I'll call this the Galena Book of History to Date
>
> 2. Tab 2- ***Take a closer look at the last 4 months of Abstral sales, so basically, who has been keeping food on our table as of late…I'll call this our WARM list and closest to Galena Friends and Family***
>
> 3. Tab 3- ***I'm a pictures guy, and this speaks to our top 25 prescribers. This group owns the chunk of the GALE business. When they're trending down, we're down…when they're up, we're up. This goes back to the theory that we need more prescribers as we can't put all of "our eggs" in this basket of 25 prescribers and you can clearly see the impact they this group has had on us in January…***I call this list, the CODE RED, and FIX IT NOW…My bat phone is ready to assist with any of these customers and I am more then happy to get in front of them as time permits and have the direct conversation to support your needs. ***Make sure this group is retrained on GPS & our PAP program.*** I witnessed a practice this week, which is on this list, that needed help in these areas. We simply can't assume our folks know or remember, as think about it, they have to remember these for every drug they prescribe.

4. Tab 4- The TRUTH- list every prescriber's growth or decline from December or January. If you want to know why we're down, and who's down, here it is in LIGHTS. ***I am going to request that by next Wednesday, we have touched every customer on this list, and please report the individual findings to your RSD's. This is a great way to recapture what you rightfully have earned….I call this list, the 100% to plan list, you get these folks turned around, and you'll be headed towards your quota.***

[Emphasis added.]

The spreadsheet attached to Mr. Corin's email listed Dr. Xiulu Ruan as the highest prescriber of Abstral in the country, with 1,184 Abstral prescriptions written from fourth quarter 2013 through fourth quarter 2014. The spreadsheet lists Dr. John Patrick Couch as the second largest Abstral prescriber in the country, with 591 Abstral prescriptions written from fourth quarter 2013 through fourth quarter 2014.

80. CW3 explained that Galena would circulate Risk Evaluation and Mitigation Strategy ("REMS") reports for Subsys (Abstral's competitor drug) that Galena received from pharmacies. The REMS reports were lists that the FDA required each pharmacy to keep in managing the known or potential risks associated with a dispensed drug. CW3 provided a July 14, 2015 email wherein Guardian Pharmacy had sent its REMS report for Subsys directly to David Corin (Galena' National Sales Director); Corin then circulated the REMS report for Subsys to Galena's Regional Sales Manager, Danielle Goodin, who sent it to CW3 with the instruction to "visit" the doctors listed in the report. According to CW3, the REMS report listed every prescriber of Subsys in CW3's territory.[4] CW3 explained that the doctors on the list were mainly primary care doctors, not oncologists. "I knew I was being challenged to go off-label," CW3 said. ***CW3 explained that at that time Galena knew that Insys (the company that owned Subsys) was openly buying pain***

[4] CW3's account is corroborated by an internal Galena document, which tracked all Abstral prescribers and which noted whether those prescribers received payments from Insys. This document was presented in the criminal trial against Dr. Couch and Dr. Ruan. *See infra*; *see also* Exhibit 1.

doctors, and yet Galena wanted its sales representatives "to chase those prescriptions." CW3 said he/she began receiving emails whenever anyone in CW3's territory prescribed Subsys because Galena "wanted you to steal the prescriptions." CW3 saved the email because CW3 said "there was something fishy" about how Galena was marketing Abstral and wanted to protect himself/herself.

81. CW3 also provided a July 20, 2015 email from David Corin (Galena's National Sales Director), ***copying Defendant Lento***, in which Mr. Corin discussed the disappointing July sales numbers. As part of the email, Mr. Corin stated:

> I want to be here till the "lights turn off," but ***if we don't do our part and drive business, the "lights will turn off."*** We simply in many cases (not all), aren't holding up our end of the bargain. The goal is to be an ASSET to the organization, not a LIABILITY.

[Emphasis added].

82. CW3 decided to leave Galena in August 2015, shortly after the above email. CW3 explained that before leaving Galena, CW3 participated in an exit interview with Human Resources. CW3 said that during the exit interview, CW3 told the Human Resources representative that CW3 was ***"encouraged to get prescriptions off-label" and to "chase prescriptions whether they were for cancer pain or not."*** CW3 said that the Human Resources worker asked if CW3 would be willing to talk to Defendant Schwartz about these issues, to which CW3 said that he/she would. However, according to CW3, Defendant Schwartz never contacted CW3 to discuss the issues.

83. CW3 recalled that the territory business manager with the highest sales was in Alabama, where two doctors who operated pain clinics went to jail for illegally prescribing Abstral and Subsys.

b. Evidence Presented During the Criminal Trial Against Drs. Ruan and Couch

84. David Corin (Galena's National Sales Director) testified as part of the criminal trial against Drs. Ruan and Couch. David Corin explained to the jury that ***Galena kept "an internal document that [Galena] would send out on a quarterly basis with all of our prescribers in the***

country, how many prescriptions they had written each quarter." According to the internal Galena document, from third quarter 2013 through fourth quarter 2014, Drs. Ruan and Couch were the largest prescribers of Abstral, with Dr. Ruan as the number one prescriber and Dr. Couch as the number two prescriber. *See* Exhibit 1, attached hereto. The ***third highest Abstral prescriber was Dr. Rho***, who was a ***"good friend" of Dr. Ruan and who was also a Galena shareholder,*** as Dr. Ruan explained in an ***email he sent to Defendant Bernarda, which was copied to Defendant Lento***. *Id.* From third quarter 2013 through fourth quarter 2014, ***Dr. Ruan wrote 1,302 prescriptions*** for Abstral, ***Dr. Couch wrote 649 prescriptions*** for Abstral, ***and Dr. Rho wrote 611 prescriptions*** for Abstral. *See* Exhibit 1. By comparison, ***the next highest prescriber*** of Abstral (*i.e*., the fourth highest Abstral prescriber in the country) during that same period ***wrote only 153 prescriptions*** for Abstral. *Id.* In other words, the fourth highest prescriber of Abstral in the country wrote only about 11.7% as many Abstral prescriptions as Dr. Ruan, only about 23.6% as many Abstral prescriptions as Dr. Couch, and only about 25% as many Abstral prescriptions as Dr. Rho. Thus, as David Corin (Galena's National Sales Director) confirmed, the only doctor "in the ballpark with" Drs. Ruan and Couch was Dr. Rho—another "pain management doctor" who was a known shareholder of Galena and who predominately treated, and prescribed Abstral to, non-cancer patients. Notably, the internal Galena document that kept track of all Abstral prescribers also noted whether the Abstral prescribers received payments from Insys. *See* Exhibit 1. David Corin confirmed that Galena's internal document tracked which Abstral prescribers "were paid by Insys" and explained that "for many doctors we want to see if they've been compensated by [Insys]."

85. Defendants knew, encouraged, and incentivized doctors, including Dr. Ruan, to prescribe Abstral to predominantly non-cancer patients. Indeed, according to emails from October 2013 between ***Defendant Lento*** and Dr. Ruan—emails that were copied to ***Defendant Schwartz***, Allan Valmonte (Galena's Director of Clinical Affairs), and David Rowan (Galena's Regional

Business Director)—***Defendant Lento*** on behalf of Galena encouraged Dr. Ruan to enroll non-cancer patients in Galena's "RELIEF" program. David Corin (Galena's National Sales Director) said the purpose of the "RELIEF" program was to track how patients taking Abstral were doing with the drug; however, the program also conveniently paid doctors $500 for every patient the doctors enrolled in the RELIEF program. When Dr. Ruan explained that he could not participate in the RELIEF program because his "practice does not have very many patients who qualify" (*i.e*., does not have cancer patients), ***Defendant Lento*** corrected Dr. Ruan and tried to persuade Dr. Ruan to enroll his non-cancer patients in the program, saying:

> I was surprised to receive this note today via Neil. I had thought that you were very excited to participate in Galena's RELIEF Registry. I believe there might exist some confusion on patient eligibility. Would it be possible to discuss at your earliest convenience? ***I'm copying Mark Schwartz***, the Galena COO, and Allan Valmonte, the director of clinical affairs, and Dave Rowan regional business director. Thanks for your consideration.
>
> [Emphasis added.]

David Corin (Galena's National Sales Director) ***confirmed that Dr. Ruan's stated reason for not participating in the RELIEF program was that Dr. Ruan said "<u>he doesn't have many cancer pain patients</u>."*** However, as David Corin explained, Dr. Ruan misunderstood the program's eligibility because Galena's RELIEF program actually enrolled both "cancer ***and non-cancer patients***." In other words, Galena paid doctors for prescribing Abstral even when Galena knew that the patients receiving the prescription were ***not cancer patients***. In the DOJ press release announcing its settlement with Galena, the DOJ referred to the RELIEF program as "nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral."

86. Thus, since at least October 2013, ***Defendant Schwartz and Defendant Lento*** (along with others from Galena) knew that PPSA did not have cancer patients but instead prescribed Abstral for off-label purposes. Moreover, Defendants were well aware that PPSA was ***not*** a cancer treatment

facility and that Drs. Ruan and Couch were ***not*** oncologists (*i.e*., cancer specialists). Indeed, Justin Palmer, a nurse practitioner at PPSA from July 2010 until it was shut down in May 2015, admitted that the vast majority (if not all) of PPSA's Abstral prescriptions were written to non-cancer patients, explaining that "we didn't have many cancer patients" and that for the entire period "from 2011 to 2015," he had seen maybe "10 or 15 active cancer patients." As Justin Palmer testified, "we didn't have that many cancer patients. I mean, I used it, I prescribed it for migraines that, you know, weren't responsive to other things. And if I could, I would give it to the patients for breakthrough pain…." Bridgette Parker, another nurse practitioner at PPSA from 2012 until its shutdown in May 2015, also testified that Drs. Ruan and Couch prescribed Abstral to non-cancer patients even though that was not what the drug's indication. "[I]t was used off label a lot, you know, ***for anything we could use it on***," Ms. Parker testified. Ms. Parker further testified that she thought the off-label uses for which Dr. Ruan and Dr. Couch prescribed Abstral were inappropriate, saying "I felt that it was used often when it shouldn't be." Ms. Parker also confirmed that both Dr. Ruan and Dr. Couch "encouraged" her to prescribe Abstral.

87. However, despite the fact that PPSA was consistently (if not exclusively) prescribing Abstral to non-cancer patients (regardless of legitimate medical need), Defendants continued to actively promote and encourage Dr. Ruan and Dr. Couch to prescribe Abstral for off-label purposes. Justin Palmer (nurse practitioner at PPSA) testified that executives and representatives from Galena frequently came to PPSA to meet with Dr. Ruan and Dr. Couch: "[T]hat was commonplace, somebody coming from, you know, Abstral or Galena" to meet with Dr. Ruan and Dr. Couch. Mr. Palmer explained that he knew the executives and representatives were there because he saw them at the office and would sometimes meet them. Indeed, ***Defendants Schwartz and Lento***, along with other Galena representatives, frequently communicated with Drs. Ruan and Couch and even traveled to Mobile for promotional visits with the two doctors. Indeed, among the emails introduced as part

of the trial were emails from December 18, 2014 between Defendant Lento, David Corin, and Defendant Schwartz's assistant discussing how to record Defendant Schwartz, David Corin, and Jeff Palmer's dinner with Dr. Ruan, with Defendant Lento stating that he has located Dr. Ruan's provider identification number in Galena's system "many times."

88. For example, on February 25, 2014, ***Defendant Lento*** (Senior Vice President of Oncology Commercial Operations), along with David Corin (National Director of Sales), took a trip to Mobile to visit with Drs. Ruan and Couch who were upset with the Company because the stock price had dropped after certain Galena insiders made massive stock sales—actions that became the subject of a Cease and Desist Order by the SEC. This upset Dr. Ruan and Dr. Couch because they had each accumulated large amounts of Galena stock. David Corin explained that he knew Drs. Ruan and Couch were upset about the insider sales because "***[t]hey sent <u>several emails</u> to my boss, whose name was <u>Chris Lento</u>, and others in the organization***. And I was—I had been forwarded those messages." According to Corin, Drs. Ruan and Couch demanded "that Galena fire the board of directors, fire the CEO, and a change in leadership." Corin said that ***the demands of Drs. Ruan and Couch were taken seriously by Galena "[b]ecause they were [Galena's] highest Abstral prescribers"*** and were, Corin agreed, "important individuals for Galena." Indeed, Galena's CEO Mark Ahn was ultimately fired.

89. ***Defendant Schwartz***, Galena's CEO, made at least two trips to Mobile to visit with Drs. Ruan and Couch during the Class Period: one trip in November 2014 and one trip in February 2015. David Corin explained that Defendant Schwartz made these trips to Mobile "[b]ecause Dr. Ruan and Dr. Couch wanted to meet with him [Schwartz]." According to Corin, **"*[i]t was demanded by Dr. Ruan that he [Schwartz] meet with him [Ruan].*"**

90. Corin made several other trips to Mobile to visit Drs. Ruan and Couch, including trips on September 24, 2014, January 20, 2015, and April 21, 2015. According to Corin, "***[Schwartz]***

wanted us [Galena representatives] to be more consistent in how often we came" to visit Drs. Ruan and Couch. Corin explained that ***"[Schwartz] wanted us to have a more regular cadence in our visits" to Drs. Ruan and Couch*** "[b]ecause other companies were visiting consistently and the higher-ups in those companies, as well – from CEOs to most C-level employees. It was important that we had a presence as well." Corin confirmed that other companies, including Insys, sent their CEOs and other high-level people to meet with Dr. Ruan and Dr. Couch, and that this was part of "what prompted more meetings or the need for more regular meetings [with Drs. Ruan and Couch] from executives at Galena." Corin explained that Dr. Ruan "made clear that we weren't giving them the same attention that other customer – other companies were." Corin elaborated that "[h]e ***[Dr. Ruan] explained it very clearly that we weren't doing enough. As a business, we weren't listening to them [Dr. Ruan and Dr. Couch] enough and we weren't going to be successful***."

91. Defendants' frequent trips and meetings with Drs. Ruan and Couch (as well as the kickbacks paid by Galena to Drs. Ruan and Couch pursuant to the rebate agreement, discussed *infra*) constituted illegal promotion of Abstral for off-label purposes. Defendants knew that Drs. Ruan and Couch treated almost exclusively non-cancer patients. Defendants, however, repeatedly and continually promoted Abstral to Drs. Ruan and Couch, and Defendants encouraged and offered incentives to these doctors to continue prescribing Abstral for off-label purposes. Indeed, Defendants actively sought to help Drs. Ruan and Couch get prior authorizations for their Abstral prescriptions to non-cancer patients, and even flew Galena representatives to visit with Drs. Ruan and Couch about how to get insurance coverage for their off-label Abstral prescriptions. For example, David Corin's January 20, 2015 trip to Mobile was to "introduce Dr. Ruan and Dr. Couch to Steven Brennan" who "was responsible for [Galena's] GPS program, which was our prior authorization program."

3. Defendants Violated the Anti-Kickback Statute By Paying Illegal Kickbacks to Abstral Prescribers

92. David Corin (Galena's National Sales Director) first met with Dr. Ruan in November 2013, when he, along with Allan Valmonte (Galena's Director of Clinical Affairs) and Jeff Palmer (sales representative from Galena), traveled to Mobile to take Dr. Ruan to a dinner meeting. ***During the meeting, Dr. Ruan "talked about what a high prescriber he was of all the products in the class and recommended that it would be good for Galena to have him as a speaker."*** Mr. Corin explained that after the meeting, ***Dr. Ruan "asked our sales representative if he could be – rather than paid a speaking fee, to be paid in [Galena] stock."*** Dr. Ruan made the request for stock compensation to Galena's "sales representative who then asked the question up the ladder."

93. Moreover, ***according to Corin, Dr. Ruan expressed at "[e]very single meeting"*** that "[h]e was very upset with the company that we [Galena] didn't support him the way other companies did." Dr. Ruan expressed that Galena was not spending enough time with him and "[t]hat we didn't do enough as a company to support physicians."

94. As David Corin further testified, in 2014, "the company and C&R Pharmacy [Dr. Couch and Dr. Ruan's pharmacy] partnered on a marketing services agreement," which was "also known as the rebate agreement." Galena and C&R Pharmacy executed the agreement in October 2014. The prosecution entered the marketing services/rebate agreement into evidence, and as the document indicated and as Corin testified, the rebate agreement was signed by ***Defendant Schwartz*** on behalf of Galena. Under the rebate agreement, Galena would pay C&R Pharmacy a certain percentage for the prescriptions of Abstral the pharmacy sold. According to the rebate agreement, the percentage Galena was to pay C&R Pharmacy ranged from 8.75% to 20%, depending on the prescription dollars C&R Pharmacy sold in a given month. As Corin explained, "[t]he average prescription [of Abstral] could be several thousand dollars. For the higher doses, you can get into the $10,000 range." Corin confirmed that "when this agreement went into place, C&R Pharmacy

would earn more money from filling Abstral prescriptions." Corin said that he was aware that Drs. Couch and Ruan owned C&R Pharmacy. The DOJ would later allege in a lawsuit filed in the District of New Jersey that the rebate agreement was an illegal kickback given in exchange for writing prescriptions for Abstral. *See supra*.

95. As Justin Palmer (nurse practitioner at PPSA) testified, "C&R [the pharmacy owned by Drs. Couch and Ruan] was part of PPSA, at least in my mind, and it was connected to the building." Mr. Palmer further testified that the PPSA patients essentially always got their Abstral prescriptions filled at C&R Pharmacy, which was connected to the PPSA clinic. According to Mr. Palmer, most pharmacies did not carry Abstral because it was so expensive: "It was such an expensive drug, that nobody else really carried it and we did." Thus, by providing percentage payments to C&R Pharmacy (owned by Drs. Couch and Ruan) for the prescriptions of Abstral filled there, <u>***Galena was paying Drs. Ruan and Couch for the prescriptions of Abstral they wrote—the definition of a kickback***</u>. Indeed, ***David Corin (Galena's National Sales Director) confirmed that the rebate agreement was made*** "***in order to add additional profit to C&R's prescrib[ing] or dispensing of Abstral***." In other words, Galena entered into the rebate agreement with C&R Pharmacy to incentivize Drs. Couch and Ruan to write more prescriptions for Abstral and to write those prescriptions to patients Galena knew to be non-cancer patients. The rebate agreement achieved its intended purpose of driving up Abstral prescriptions and Galena revenues, as Mr. Corin admitted that ***the number of prescriptions for Abstral from Dr. Ruan and Dr. Couch increased after the rebate agreement went into effect***.

96. FBI agent Amy White also testified during the criminal trial of Drs. Ruan and Couch. As part of Agent White's testimony, the prosecution introduced a Federal Reserve document reflecting ***a February 18, 2015 wire in the amount of $97,924 from Galena to C&R Pharmacy's***

Wells Fargo bank account. Agent White testified that the FBI believed the $97,924 wire to be a payment pursuant to the rebate agreement.

97. Moreover, David Corin (Galena's National Sales Director) testified that ***Galena had rebate agreements like the one with C&R Pharmacy with several oncology dispensing clinics and with two pharmacies that were non-oncology dispensing clinics (meaning "not clinics in cancer centers")***. According to Corin, the agreements would essentially be the same "the only difference is it's C&R."

98. Other evidence admitted at the trial revealed that Galena also invited both Drs. Ruan and Couch to attend Galena's Advisory Board Meetings. Emails, including an email from December 5, 2013 exchanged between Dr. Ruan and ***Defendant Lento***, reflect the intention that Dr. Ruan would act in an "advisory" capacity for Galena, with Dr. Ruan stating: **"*I am very excited about the opportunity to be involved with Galena at the highest advisary/consultatory level, <u>as we discussed in our previous conversations</u>*."** Dr. Couch attended at least one of Galena's Advisory Board Meetings, for which, according to the US Department of Justice, Galena paid Dr. Couch $5,000 plus expenses. According to other emails presented during the trial, Dr. Ruan ultimately decided not to attend Galena's Advisory Board Meeting due to concerns that he might hear inside information that would prevent him from freely trading his Galena stock.

4. Defendants Conspired with Drs. Ruan, Couch, and Rho to Manipulate Galena Stock

99. Beginning in November and December 2013, Drs. Ruan and Couch began purchasing large amounts of Galena stock. In fact, according to evidence presented during the criminal trial, the two doctors expended more than ***$1.6 million*** in purchases of Galena shares in a little over a 6-month period.

100. Since well before the start of the Class Period, Defendants were undeniably aware that Drs. Ruan, Couch, and Rho (Dr. Ruan's "good friend" who also communicated directly with

Galena officers) were trading in Galena stock at the same time that they were the three largest Abstral prescribers—by huge and inordinate margins wherein these three doctors accounted for approximately 40% of all Abstral sales, Galena's only source of income. *See* Exhibit 1, attached hereto.

101. For example, on January 20, 2014, Dr. Ruan sent ***Defendant Lento*** an email entitled "advisory board meeting." In the email, Dr. Ruan wrote:

> Hi, Chris, it seems that I will not be able to make this weekend's advisory board meeting. The reason is ***I recently purchase some stocks from Galena on line***. Now, if I get involved with the co at advisory board level, then I will be considered "insider", right? If so, ***there will be a lot of restrictions and regulations on how these stock can be traded.*** Also, there may be some legal trouble once I know more about the Co and owns stocks. At the current level, I know no more than general public, therefore, ***there is no risk for me <u>to trade the stocks I purchased</u>***. I have sent some information to my lawyer to find out the legality of this, while owning stocks and participating the board meeting. He has not emailed me yet. So, I figured I just want to let you know. Hope everything is well and hope you all have a successful meeting this weekend. I have not signed the agreement yet with Galena, so I am not an "insider". Have a great weekend!
>
> [Emphasis added.]

Thus, ***since at least January 20, 2014, Defendant Lento knew that Dr. Ruan had purchased Galena stock and was looking to trade that stock without "risk" or "restrictions."***

102. Indeed, Dr. Ruan's decision not to participate in Galena's Advisory Boarding meeting was entirely due to his desire to be able to trade stock since ***he "plan[ned] to sell quick on the side."*** As Dr. Ruan said in a January 18, 2014 email to Dr. Couch:

> Pat, I am reconsidering whether I should go to the next weekend's Galena Advisory Board meeting. I am concerned that once I am involved with them at that level, then I am considered "insider" and subjecting myself to more restrictions and regulations, etc. What do you think? Remember Martha Stewart went to jail for 6 months after avoiding $46K loss in stock? As ***we both have purchased a good number of stocks <u>and plan to sell quick on the side</u>***. It will save me a lot of worries if I am not involved with the Co as their advisory board member so that know no more than the general public. I will check with my attorney Tom Galloway for his advice. You may ask Boe's opinion on this too. I just want to make sure neither us or PPSA gets involved in a bad way! May be I am paranoid, but since ***we both have purchased some stocks and we use their products more than others***. So, I am

> waiting for Tom to give me his opinion on this before I made my finial decision whether I will go or not. Just a few links below regarding this issue.
>
> [Emphasis added.]

103. In an email he sent to Dr. Couch on February 2, 2014, Dr. Ruan further discussed the doctors' plans to manipulate Galena stock while "play[ing] a big role" in propping up the stock price by overprescribing Abstral in a "dominant fashion." Dr. Ruan's email read, in relevant part:

> When I read about the history of lnsys, considering their initial IPO on May 7, 2013 at $8, and within 7 months, it hit $60, despite the Subpoena by inspector general, ***I believe Gale has much better chance of hitting much higher. So, I will hold mine for at least a year, giving it 3 quarters to grow.*** It certainly has a chance be close to Insys in term of market share.
>
> Also, considering I have lost millions on real estate, I could afford to lose all mine in this, but ***there is a good chance that it will bring the most. I like the chances. I will wait till I see at least 3 quarters. <u>This is the product we can play a big role. I am sure we can with Zogenix, but not in this dominant fashion as many other providers can do the same, but with Abstral.</u>***
>
> So, I believe it is worth the risk!
>
> [Emphasis added.]

104. In emails Dr. Ruan sent to a friend on February 17, 2014, Dr. Ruan further described his belief that "there will be a major market share taking over, which may drive the stock up" and his plan to "hold[] them for 1.5 years, give Galena enough time to eat the market share from Insys, as I believe it will."

105. According to testimony from Justin Palmer, a nurse practitioner at PPSA who also bought stock in Galena at the advice of Dr. Couch, ***PPSA put more patients on Abstral <u>after</u> Dr. Ruan, Dr. Couch, and Mr. Palmer bought Galena stock***. Mr. Palmer's testimony included the following exchange:

> Q: ***Did you have occasion, after you bought Galena stock, to discuss prescribing Abstral with Dr. Couch?***
>
> A: We -- we did. ***We talked about -- I mean, patients that were, you know, candidates or suitable candidates for that drug.***

Q: ***Did you begin to put a number of individuals on Abstral, number of patients?***

A. ***Yes, yes.***

Q: ***Had you been encouraged to do that by anyone?***

A: I don't know if I would say encouraged. But, you know, ***it was suggested to find people that could benefit or -- I guess so, I mean.***

Q: ***What was the purpose of that, finding people to put on Abstral?***

A: ***Well, I mean, we did have shares in the company. So --***

Q: ***You and who?***

A: ***Dr. Couch and, I guess Dr. Ruan. And it was -- you know, it would have been financially a good decision.***

Q: For you?

A: For me.

Q: And for who else?

A: For Dr. Couch and Dr. Ruan.

Q: ***Did the Abstral prescriptions at PPSA go up during that time initially?***

A: ***Yes.***

Q: ***After you bought stock?***

A: ***Yes.***

Mr. Palmer again later admitted that PPSA "started writing more Abstral" prescriptions after he, Dr. Ruan, and Dr. Couch purchased Abstral stock and explained that the increase was ***not*** due to an increase in cancer patients:

Q: ***Was there some outbreak of people coming to PPSA with cancer during this period of time that you're aware of?***

A: ***No***.

As Mr. Palmer had previously testified, PPSA "didn't have many cancer patients," and for the entire period "from 2011 to 2015," he had seen maybe "10 or 15 active cancer patients."

106. On March 16, 2014, Dr. Ruan emailed ***Defendant Bernarda***, copying ***Defendant Lento***, in which Dr. Ruan requested that he, Dr. Couch, and Dr. Rho be given a chance to speak with Galena's Board of Directors. Dr. Ruan stated the following:

> Remy, hope you have had a good weekend! ***I have had quite a few conversations with a few physicians who have all invested in your company.***
>
> ***Dr. James Rho, a good friend of mine, who is an interventional pain specialist in CA and also a strong believer in Abstral and an expert in TIRF, is interested in joining the conference on Thursday with you and your BOD.*** I believe he should be of no stranger to your Abstral sales team, even if you may not know him. As a matter of fact, he has shared with me many positive feedback from using Abstral since last Fall. ***Just like Dr. Couch and I, Dr. Rho*** also believes Galena's product and its pipeline, and therefore ***a share holder*** as well.
>
> I had lengthy discussion with Dr. Rho and Dr. Couch this weekend. ***We feel that if will be very beneficial if we could attend this conference together, have a honest discussion with the Board of Director(s) of Galena, to express our feeling, concerns, opinions/recommendations, as <u>we are not only share holders, but also your clients, and customers</u> to some extent***. I hope that is OK with you and your Board of Director(s).
>
> Thank you very much for your kind help!
>
> [Emphasis added.]

107. In response to Dr. Ruan's email, Defendants facilitated ***a call for Drs. Ruan, Couch, and Rho to speak with a member of Galena's Board of Directors, Bill Ashton, and with <u>Defendant Bernarda</u>*** if she could participate. Indeed, ***Defendant Bernarda*** sent Dr. Ruan a response email in which she stated, in pertinent part:

> That sounds great and we appreciate your support. ***From Galena, you will be speaking with our Board Member, Bill Ashton***, and his bio is below. ***I am traveling, but will try to join the call as well***. Dr. Rho, here are the conference call details….
>
> [Emphasis added.]

108. Thus, despite knowing that the three highest prescribers of Abstral (by significant margins) were also trading Galena stock, Defendants responded by allowing these doctors to have even greater sway over the Company by arranging a call in which the doctors could voice their "feeling[s], concerns, opinions/recommendations" to a member of Galena's Board of Directors and one of Galena's senior executive officers. As explained in a separate email from Dr. Ruan to Dr. Rho, "[t]he purpose of this talk is to express our opinion to push them to replace their CEO" and ***"to give them the impression that if they do not do it, we will switch to other Cos and its products altogether (I will use [sic] express this in a indirect way, but enough for them to understand what we will do if they don't do it)" since "as you know very well, <u>they know who we are</u>…."*** Dr. Ruan further explained in the email: "***Since you [Dr. Rho], Dr. Couch, and I are all share holders of the [sic] and together <u>we represent a very significant portion of their business</u>***, we have a better chance of making it if team up together to get this done."

109. On April 14, 2014, Dr. Ruan again emailed ***Defendant Bernarda***, copying ***Defendant Lento***, writing the following, in reference to Galena's insider trading scandal:

> Hi, Remy, how are you!? lt has been a while since we last communicated. I hope this email could you (assuming you have not left yet).
>
> I dont even know where to start! In my life, I have never seen something like this, when a truly healthy, promising Co (Galena), with unique pipeline and solid a FDA approved product, employees with good morale and working ethics, has been totally ruined, not by natural disaster, politicians, or competition, but by its own executive officers and its board of directors, because of their blatant, insatiable greed and selfishness! To them, everything can be sacrificed, as long as their pockets are filled up! They dont give a damn about other shareholders' interest, the market, the public trust, the reputation of the company, their employees, and their customers, and the patients! What bothers everyone is the fact that the supervising BOD and its executive officers created this mess in cahoots! ***I agree with many of other share holders that the executive team and BOD need to be replaced ASAP***, as no one would like to see Galena end up filing bankruptcy!! No one will believe whatever your CEO or BOD say or do! Their presence with Galena will be enough to wipe out any confidence/trust/hope from the public which is what needed to save Galena! The only thing that may save the Co is the change in the executive team and its BOD!!! This needs to happen and nothing can replace it!!! No one can/will develop any trust in them!

[Emphasis added.]

110. As Corin had testified, ***the demands of Drs. Ruan and Couch were taken seriously by Galena "[b]ecause they were [Galena's] highest Abstral prescribers" and were, Corin agreed, "important individuals for Galena."*** Indeed, Defendant Ahn was fired from Galena in August 2014.

111. In allowing, and even encouraging and enabling, these three individuals to dictate much of Galena's success while simultaneously failing to disclose their stock ownership as required by the Sunshine Act, Defendants were complicit conspirators in these doctors' attempts to manipulate Galena stock for their personal profit. In fact, Dr. Ruan described his desire to be able "***<u>to trade the stocks [he] purchased</u>***" without "risk" or "restrictions" directly to ***Defendant Lento*** in January 2014. Despite that knowledge, Defendants continued to court Drs. Ruan and Couch—making frequent trips to Mobile to take them to dinner, permitting Drs. Ruan, Couch, and Rho to speak directly with Galena officers and directors, placing Dr. Couch on Galena's Advisory Board, assisting the doctors in getting Abstral covered by insurance via Galena's GPS program, and establishing a rebate agreement with C&R Pharmacy in order to get Drs. Ruan and Couch kickbacks for the Abstral prescriptions they wrote. Moreover, Defendants assisted in covering up these doctors' ownership of Galena stock by failing to disclose their ownership as the Company was required to disclose under the Sunshine Act.[5] Defendants were complicit in these doctors' stock manipulation scheme because the scheme benefitted Galena. Specifically, Defendants used the outsized revenues (resulting from the inflated Abstral prescriptions) to fund operations of the Company and used the overvalued stock to obtain equity financing.

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[5] Https://OpenPaymentsData.CMS.gov makes publicly available information that Galena was required to submit to the Centers for Medicare and Medicaid Services, including whether physicians owned Galena stock. However, the information on this website indicts ***no ownership*** of Galena stock by Drs. Ruan, Couch, or Rho during 2013, 2014, or 2015.

112. Defendants Ahn, Dunlap, and Bernarda were defendants in an earlier securities fraud action, *In re Galena Biopharma, Inc. Sec. Litig.*, No. 3:14-cv-367-SI (D. Or.), which alleged that Galena and certain of its officers and directors committed a classic "pump and dump" manipulation scheme, whereby they paid third-party newsletter writers to post articles touting Galena stock. The articles, which purported to be authored by credible investment professionals, never disclosed that they were paid promotions, and Galena never disclosed the Company was using such stock promoters that on their face appeared to be independent. As a result of the third-party promotions, Galena's stock price nearly quadrupled, and Galena insiders quickly sold almost all their stock, reaping approximately $16 million in personal profits. The parties reached a settlement of these claims. On April 10, 2017, the SEC announced it had reached a settlement with Galena for charges the SEC had brought stemming from this stock manipulation scheme. As part of the SEC settlement, Galena and its former CEO, Defendant Ahn, agreed to cease and desist from future securities laws violations, and Ahn was prohibited from acting as an officer or director of any registered issuer of securities. Defendant Ahn agreed to disgorge $677,250, pay prejudgment interest of $67,181, and a civil penalty of $600,000. Galena agreed to pay a civil penalty of $200,000.

5. Defendants Knew That Abstral Sales Were Artificially Inflated and Unsustainable

113. Abstral was a Schedule II drug, which is the strongest medication prescribable. As discussed *supra*, the government in recent years has taken an increasingly strict and active stance against the over-prescription and off-label prescription of such powerful and addictive opioids.

114. According to the accounts of the confidential witnesses and the testimony provided in the trial of Drs. Ruan and Couch, Galena's Abstral sales were overwhelmingly driven by Galena's practices of promoting Abstral for off-label purposes. Such a tactic by Galena had the effect of temporarily and artificially inflating the sales of Abstral. As Defendants knew, or should have known in the absence of extreme recklessness, the inflated Abstral sales that were predominantly based on

off-label prescriptions (many of which were for non-legitimate medical purposes) to non-cancer patients were short-lived and wholly unsustainable.

115. On May 19, 2014, months before the start of the Class Period, the Centers for Medicare and Medicaid Services ("CMS") announced that the federal government had expanded the authority of CMS. Under the new authority, CMS had the ability to compel health providers to enroll in Medicare to order medications for patients covered by its drug program, known as Part D, to give Medicare the opportunity to ensure that Part D drugs were only being prescribed by qualified individuals and for appropriate uses. The grant of new authority also allowed CMS to revoke Medicare enrollment for abusive prescribing practices and patterns.

116. As DEA special agent Michael Burt explained during his testimony as part of the criminal trial against Drs. Ruan and Couch, Medicare would not pay for TIRF prescriptions, like Abstral, that were written for non-cancer pain. In fact, Medicare extensively audited all Medicare Part D carriers for filling and paying for TIRF drugs such as Abstral. As part of these audits, if Medicare determined that a prescription had been given to a non-cancer patient, it required that a refund be made to Medicare.

117. According to evidence presented during the trial of Drs. Ruan and Couch, by September 9, 2014, PPSA had been advised that Medicare was auditing TIRF prescriptions and that "[a]ll patients must meet the criteria of an active cancer pain diagnosis only" in order for the prescription to be covered under Medicare, Part D. Dr. Ruan acknowledged the "widespread audit" coming from Medicare, and submitted a letter to a Medicare representative on September 23, 2014 in an attempt to "educate" CMS on prescribing TIRFs, such as Abstral, for non-cancer pain. Within the same day, September 23, 2014, Medicare responded to Dr. Ruan's email and advised:

> At this time the only approved indication for TIRF drugs for coverage under Medicare Part D remain for the treatment of ***cancer pain***. Peer review articles are not acceptable for drug coverage under Medicare Part D. In the future if TIRF

> drugs receive additional indications by the FDA or if the official compendia support other issues, future audits will reflect these additional indications.
>
> [Emphasis added.]

118. Medicare's express refusal to cover Abstral prescriptions for non-cancer pain was particularly problematic for PPSA, as the clinic prescribed its Abstral to patients with back, neck, and joint pain, migraines, and other non-cancer pain. Tellingly, however, DEA agent Burt testified and discussed evidence showing that Dr. Ruan had neck pain, which he described in an email as "worse than 95 percent of the patients I see in my clinic," yet Dr. Ruan had not prescribed himself, nor had he taken, any TIRF for his pain. Indeed, despite Dr. Ruan having represented to Medicare that "breakthrough pain in cancer and non-cancer are very similar and only TIRF products are the drug of choice," DEA agents found no evidence suggesting that Dr. Ruan had ever taken a TIRF fentanyl product for the pain he described as "worse than 95 percent of [his] patients."

119. Eventually, the illegal practices of Drs. Ruan and Couch in overprescribing and dispensing Abstral were brought to an end. As David Corin testified:

> Q: Do you know what, if anything, occurred in ***late May of 2015*** regarding Dr. Ruan and Dr. Couch?
>
> A: ***Our understanding is that their practice was shut down.***
>
> Q: Following the shutdown of their practice, what happened to prescriptions for Abstral?
>
> A: In regards to Dr. Ruan and Dr. Couch?
>
> Q: In regard to overall number of prescriptions written for Abstral after Dr. Ruan and Dr. Couch's practice was shut down?
>
> A: ***Our volume dropped.***
>
> Q: Did it drop by a little bit or did it drop significantly?
>
> A: ***Significantly***.
>
> Q: What then happened to Galena's ability to promote Abstral?
>
> A: We were limited because we couldn't make up that revenue. And eventually Galena was forced to sell the product in December of 2015.

***

Q: At what point did you leave Galena?

A: December 31st, 2015.

Q: Did you leave on your own or were you fired?

A: The commercial team was dissolved.

Q: Why was the commercial team dissolved?

A: There were no commercial products to sell.

Q: And is that after Abstral was sold off?

A: Abstral and Zuplenz, which was our other product.

120. Defendants knew, or should have known in the absence of extreme recklessness, that Abstral sales largely supported by two pain management doctors prescribing inordinately large amounts of Abstral to non-cancer patients could not be sustained given the government's aggressive oversight of prescription opioids. Moreover, Defendants knew, or should have known in the absence of extreme recklessness, that Drs. Ruan and Couch were illegally prescribing Abstral for improper purposes. The sheer number of prescriptions being written by these two doctors when compared to other doctors was a significant red flag that could not have gone unnoticed by Defendants. *See* Exhibit 1.

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS VIOLATED SECTIONS 10(B) AND 20(A) OF THE EXCHANGE ACT AND SEC RULE 10B-5

121. Section 10(b) of the Exchange Act prohibits the "use or employ[ment], in connection with the purchase or sale of a security…[, of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe."

122. SEC Rule 10b-5, promulgated under Section 10(b) of the Exchange Act, makes it unlawful in connection with the sale of a security "[t]o make any untrue statement of a material fact

or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading."

123. Defendants violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 by: (1) making statements that were outright false, (2) omitting material information necessary to make their statements not misleading and/or (3) violating a statutory duty of disclosure.

124. The allegations of Defendants' materially false and misleading statements are divided into three categories, each independent of the other.

125. In Section V.A., below, Plaintiffs allege that Defendants volunteered statements, among other things, about Galena's business practices and revenues from Abstral and the sources of those revenues that were outright false or rendered materially misleading by the omission of material facts necessary to make such statements not misleading. The viability of alleged claims based on these alleged materially false and misleading statements is in no way dependent upon the reporting requirements set forth in SEC Regulation Item 303 (17 C.F.R. §229.303).

126. In Section V.B., below, Plaintiffs allege that Defendants volunteered statements about Galena's discontinued commercial operations (marketing and sales of Abstral) and government investigations of, and/or legal proceedings against, Drs. Ruan and Couch and Galena and its employees. Plaintiffs allege that these statements were outright false or rendered materially misleading by the omission of material facts necessary to make such statements not misleading. The viability of alleged claims based on these alleged materially false and misleading statements is in no way dependent upon the reporting requirements set forth in SEC Regulation Item 303.

127. In Section V.C. Plaintiffs allege that Defendants made certain statements in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's annual reports on SEC Form 10-K and quarterly reports on SEC Form 10-Q that included some, but omitted other, information about trends and uncertainties facing the Company

required to be disclosed under Regulation S-K, Item 303. Plaintiffs allege that the omission of this information, which was also required to be disclosed under Item 303(a), caused Defendants' MD&A disclosures to be materially misleading. These omissions also violated a statutory duty of disclosure; however, Plaintiffs allege that the statements were materially misleading independent of the violation of this statutory duty.

A. Defendants' Materially False or Misleading Statements Regarding Galena's Revenues and Business Practices

1. August 11, 2014 Statements

128. The Class Period begins on August 11, 2014. On that day, Defendants issued several materially misleading statements that touted Galena's increased revenues and market share, and attributed these gains to Galena's lawful sales initiatives and doctors' "belief in the unique benefits of Abstral," while failing to disclose that the revenues were actually the result of illegal and unsustainable practices. The materially false or misleading statements were:

a) The Company reported ***net revenue for the three months ended June 30, 2014 was $2.3 million and $4.5 million for the first half of 2014***, compared to no net revenue for the six months ended June 30, 2013, and touted that it was succeeding in its ***"strategy to build value for patients and shareholders by" among other things "[a]chieving revenue goals for Abstral."*** (Form 10-Q, signed by Defendants Ahn and Dunlap; *see also* Earnings Press Release dated August 11, 2014).

b) [Ahn:] "In addition to a strong second quarter in all programs across the Company, we've had two exciting recent announcements. ***On the commercial side, we saw continued <u>strength towards actual profitability with the implementation of our Galena Patient Services</u>, or GPS program, ensuring access and <u>strengthening our competitiveness with steadily increasing market share to 7%</u> in a market that actually declined last quarter***." (Earnings conference call, with Schwartz, Dunlap, Ahn, and Bernarda participating).

c) [Schwartz:] "Our Abstral business continues to grow and we remain excited about and committed to the brand. As a reminder, Abstral is a transmucosal immediate release fentanyl, or TIRF product, for the treatment of breakthrough ***cancer pain*** in opioid-tolerant patients. Our commercial organization continues to focus on a strategy to broaden patient and provider access to the product, while increasing profitability of the product line.

> ***There are <u>four primary factors have resulted in continued product expansion</u> and a stable business foundation upon which to build: <u>first</u>, ensuring availability, reimbursement, and insurance coverage; <u>second</u>, optimizing our Patient Assistance program; <u>third</u>, strengthening our distribution and our wholesale partnerships; and <u>finally</u>, continued development of our prescriber base. In Q2, we saw growth and improvement across a number of key metrics over Q1.***
>
> ***
>
> Our Q2 market share, as measured by Wolters Kluwer, increased to 7% of prescriptions written, despite the fact that the overall branded TIRF market declined in prescription volume over the same period. ***<u>These improvements are a direct result of our team's focus and our customers' belief in the unique benefits of Abstral</u>***." (Earnings conference call, with Schwartz, Dunlap, Ahn, and Bernarda participating in the call).

d) [Dunlap:] "Thank you, Brian, and good afternoon everyone. Net revenue from Abstral sales for the second quarter of 2014 was $2.3 million, ***an increase of 7%*** from last quarter and $4.5 million for the first two quarters of 2014. ***We've seen continued growth in market share*** and continued decline in our gross-to-net deductions, which aren't reflected in the net revenue growth this quarter, due to the timing of customer orders and wholesaler and distributor inventory control affecting our ex manufacturer sales. . . . . As Mark Schwartz also laid out, ***the Abstral franchise is growing and becoming more profitable***." (Earnings conference call, with Schwartz, Dunlap, Ahn, and Bernarda participating in the call).

[Emphasis added.]

129. Defendants' August 11, 2014 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false and misleading because while they touted Galena's net sales and revenues, they failed to disclose that: (1) these results were achieved through Galena's illegal promotion of Abstral for off-label purposes (*i.e.,* non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral; and (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two pain doctors who made up 30% of all Abstral sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks and manipulate Galena's stock. In truth, as Defendants knew, Abstral was creating increased revenues and market share as a result of Galena's illegal promotions of Abstral for non-cancer pain and the over-prescription of Abstral by at least two disreputable doctors who were writing illegal prescriptions outside the usual

course of professional practice and not for a legitimate medical purpose. This is the real reason Galena saw improvement in its market share, not "the implementation of . . . Galena Patient Services" (bullet b), Galena's ability to ensure "insurance coverage" (bullet c), or the "customers' belief in the unique benefits of Abstral" (bullet c), as represented by Defendants. Moreover, while Defendants portrayed that these revenues were sustainable (bullet a) and that "the Abstral franchise is growing and becoming more profitable" (bullet d), in reality, Abstral's revenues—which were reliant on Galena's illegal promotions and payments and doctors' over-prescriptions for off-label non legitimate medical purposes—were unsustainable, particularly in light of the government's increasing oversight of fentanyl prescriptions.

130. On August 21, 2014, Galena announced that Defendant Schwartz had been named CEO in replacement of Defendant Ahn.[6]

2. September 25, 2014 Statements

131. On September 25, 2014, Galena held a press conference during which Defendants provided updates on Abstral sales as well as the Company's initiatives. Defendants Schwartz, Dunlap, and Bernarda attended the conference, with Schwartz speaking to analysts and investors, and stating in pertinent part:

> [Schwartz:] Since our Abstral launch in October of last year, ***we have met the goals we laid out for the $1.5 million to $3 million of net revenues*** we predicted in 2013 and the successful launch of our Galena Patient Services program earlier this year. ***Over the last several weeks, we've done a thorough analysis of our Abstral program and the current state of the transmucosal immediate relief fentanyl, or TIRF, branded market. <u>Our strategy is focused on targeting oncology patients treated by both pain medicine specialists and oncologists, thus remaining true to the overall mission of the Company</u>. We recognize that <u>our approach of primarily targeting oncology practices</u> has resulted in a slow, but a consistent growth pattern that we believe <u>will result in a viable and strategic business in the long term</u>.***

[6] According to the Company, Defendant Ahn resigned "to pursue other long held personal and professional goals." In reality, Ahn was forced out because of his involvement in the insider trading scandal which ultimately resulted in him paying a substantial fine and being banned from serving as an executive officer of public companies.

***

> ***As I indicated, <u>oncology is the prime goal and mission of the Company</u> and our focus moving forward is really predicated on <u>continue to drive and build deep relationships with all elements of the oncology practice and essentially the oncology business</u>.***
>
> [Emphasis added.]

132. Defendant Schwartz's September 25, 2014 statements were materially false or misleading because they attributed Abstral's sales to "oncology patients" and stated that Galena "primarily target[ed] oncology practices" when, in truth, a large portion of the Company's sales were coming from pain management doctors who were prescribing Abstral off-label outside the usual course of professional practice and not for legitimate medical purposes. At the very least, such statements were materially misleading because they failed to disclose that a substantial portion of Abstral revenue—***thirty percent***—was generated through over-prescriptions of Abstral written by just two pain doctors who were prescribing Abstral off-label (and were doing so in an attempt to manipulate Galena stock). Such statements were also materially misleading since, as Defendants knew, revenues from Abstral were actually the result of Galena's illegal promotions of Abstral for non-cancer pain and illegal kickbacks paid to doctors, including kickbacks for prescriptions that were known to be off-label.

3. November 3, 2014 and November 5, 2014 Statements

133. On November 3, 2014 and November 5, 2014, Defendants reported Galena's third quarter 2014 results and, in doing so, issued several materially false or misleading statements:

a) Galena's press release, dated November 3, 2014, reported "***[n]et revenue for the third quarter of 2014 was $1.6 million compared to $1.2 million for the third quarter of 2013, an increase of 25%. Net revenue for the nine months ended September 30, 2014 was $6.1 million***. The third quarter of 2013 was the first quarter that the company generated net revenue." Galena's press release also quoted Defendant Schwartz as stating: "'The company continues to make excellent progress on our clinical programs, and we continue to build our commercial

franchise.'" (Press Release issued November 3, 2014; *see also* Form 10-Q filed November 5, 2014, signed by Schwartz and Dunlap).

b) [Lento:] "I will begin to [sic] Abstral, our lead commercial asset. ***Abstral is a transmucosal immediate release fentanyl, or TIRF product, indicated for the treatment of breakthrough pain in opioid tolerant <u>cancer</u> patients***. As noted in our press release, and as Ryan will review in greater detail, our Abstral net revenue was $1.6 million in Q3. As discussed last quarter, this increase in revenue was expected, and was a result of fluctuations in inventory at the wholesale and distribution level. This is not uncommon, as we're still in the first year of our product launch.

Our daily paid prescriptions or pulled through sales from our customers have continued to improve through the end of Q3, with an even stronger demand in the first month of Q4. Over time, we expect the ex-manufacturer sales to more closely reflect our daily paid prescription volume. As a reminder, Abstral is a supportive care therapy in a segmented and highly competitive market.

According to Wolters Kluwer, our market share of the branded TIRF market in September remained steady with 6% of total prescriptions. The size of the overall TIRF market has fluctuated since our launch, ***and we remain focused on <u>targeting the long-term and sustainable business</u> within the market.*** We strongly believe in the potential of Abstral because of its unique clinical attributes, which are advantageous for patients.

We have spent the first year of our launch developing strong relationships with the <u>appropriate healthcare providers who are treating the appropriately indicated patients</u>. The foundation of our Abstral strategy was built upon ensuring product access and insurance coverage for all identified patients.

***

2015 will be an important year for our commercial team, and <u>I'm confident about our prospects for continued growth and success</u>. We're focused on building a <u>long-term oncology supportive care business</u>. Knowing that having both Abstral and Zuplenz will be viewed positively by our <u>oncology focused providers</u>." (Earnings conference call on November 3, 2014, with Schwartz, Dunlap, Lento, and Bernarda participating).

c) [Schwartz:] "Thank you, Ryan. As we look back on our first year of commercial activities, we're proud of the structure we have built. While Chris highlighted some the challenges, we also know how to address and adapt to them, as the market has changed for Abstral***, our commercial team has refined our strategy <u>to ensure the long-term viability and profitability</u> of the franchise***.

We'll be taking the same expertise into our launch of Abstral. As a result, we plan to increase our Abstral revenues by over 50% next year and are setting our 2015 net revenue guidance to between $15 million and $18 million." (Earnings

conference call on November 3, 2014, with Schwartz, Dunlap, Lento, and Bernarda participating).

[Emphasis added.]

134. Defendants' November 3, 2014 and November 5, 2014 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading because: (1) they touted Abstral's revenues while attributing Abstral's sales to "appropriately indicated patients," which they explained were "cancer patients" (bullet b); (2) they stated that Galena sales were focusing on "oncology focused providers" (bullet b); and (3) they further assured that Galena's sales strategy was ensuring "long-term viability and profitability" (bullet c). Such statements were materially misleading because they failed to disclose that: (1) the touted financial results were achieved through Galena's illegal promotion of Abstral for off-label purposes (*i.e.*, non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral (including kickbacks for prescriptions that were known to be off-label); (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by <u>at least</u> two rogue pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks and manipulate Galena's stock price; and (3) for these reasons, Abstral's revenues were not sustainable, particularly in light of the government's increasing oversight of fentanyl prescriptions. Defendants misled investors that the Company's Abstral sales were sustainable through legitimate sales practices and promotions to physicians prescribing for on-label indications and/or actual medical need.

4. March 5, 2015 Statements

135. On March 5, 2015, the Company announced its fourth quarter and year end 2014 financial results and, in doing so, issued several materially false or misleading statements:

a) "***Net revenue was $3.2 million in the fourth quarter of 2014 and $9.3 million for the year ended December 31, 2014, compared to $1.3 million and $2.5 million, respectively, for the same periods of 2013***…. Dr. Schwartz continued,…[,] ['a]dditionally, ***we anticipate the commercial arm of our business to continue to grow revenue, <u>while enhancing our relationships in the oncology community</u>*** as

our development pipeline advances. ***As reported today, we recorded our strongest Abstral quarter to date, hitting above the middle of our guidance range for the year***, and with the addition of our second commercial product in Zuplenz, we expect to nearly double our overall commercial sales in 2015.'… Dr. Schwartz concluded, 'Our commercial and clinical teams have done a tremendous job over the past year to advance our multiple programs. As I assess our company, I am not only excited about the next 6-12 months, but for the ***<u>long-term prospects</u> of Galena Biopharma***.'"(Galena's March 5, 2015 press release; *see also* Form 10-K filed March 5, 2015, signed by Schwartz and Dunlap).

b) [Schwartz:] "***Our focus is on building Galena into a leading <u>oncology</u> Company.*** We established our commercial franchise as a strategic component for ***<u>long-term growth</u>, and sets a foundation for our future***. . . . ***As Chris will elaborate, the relationships that our commercial team is making now with key <u>oncology</u> healthcare providers, distributors, and managed care groups are not only extremely valuable for selling our current products, but also provide the ability to quickly add future products.*** Finally, we expect the commercial business to maximize revenues, become accretive, and provide money to the Company to help fund our development assets and minimize shareholder dilution." (Earnings conference call with Defendants Schwartz, Dunlap and Lento participating).

c) [Lento:] "Thank you, Gavin. Today I will walk you through the 2014 successes we have had with our flagship product Abstral….

As noted in our press release, and as Ryan will review in greater detail, ***our actual net revenue was $9.3 million in 2014. We achieved this number with a focused sales effort, and we are excited for continued growth of Abstral in 2015. As a reminder, Abstral is indicated for the treatment of breakthrough <u>cancer pain</u>, and it is a TIRF, or a transmucosal immediate release fentanyl, product. As Mark mentioned, Galena is an <u>oncology</u> Company, and we are <u>steadfastly focused on building Galena's commercial business within the oncology space.</u>***

…With that background, I would like to walk you through the metrics are use to evaluate our business. We acquired the US marketing rights for Abstral from Orexo and relaunched the product in the fourth quarter of 2013. ***We relaunched Abstral that had previously sold approximately $1 million over its previous 12-month period, and we were able to grow the brand to $9.3 million in net revenue in 2014. We believe that we can continue to grow Abstral***, and our successful commercialization will carry over to the relaunch of Zuplenz in Q2.

***

In addition, on slide number 21 you can see the dramatic impact of our patient assistance rule changes and our GPS services have had on increasing the average number of Abstral units dispensed per pay transaction. In December 2013, the average units of Abstral per pay transaction was roughly 42 tablets. Fast forward to December 2014, and the average number increased roughly 60% to 69 tablets per transaction. ***In addition to GPS and the program rule changes, providers have become more comfortable prescribing Abstral for their***

breakthrough <u>cancer pain patients</u>." (Earnings conference call with Defendants Schwartz, Dunlap and Lento participating).

d) [Dunlap:] "Thank you, Chris, and good afternoon, everyone. Net revenue from Abstral sales for the fourth quarter of 2014 was $3.2 million, and $9.3 million for the full year 2014. ***We're happy to say the Q4 was a record quarter for us, reflecting a 100% increase from the $1.6 million net revenue recorded in Q3 and landing us squarely within our 2014 net revenue guidance of $8 million to $10 million. We are certainly pleased with that trend and remain confident in our 2015 net revenue guidance of $15 million to $18 million, with the expectation that our Abstral business will become cash flow positive by the end of 2015 and will continue to be the key revenue driver this year***." (Earnings conference call with Defendants Schwartz, Dunlap and Lento participating).

e) "***The increase in gross revenue is also attributable to an increase in the number of Abstral prescriptions, with the fourth quarter of 2014 being the strongest quarter for our Abstral prescriptions since acquiring the product***." (MD&A section (Item 7) of Galena's Form 10-K).

[Emphasis added.]

136. Defendants' March 5, 2015 statements (in Galena's press release, Form 10-K, and earnings call) were materially false or misleading. While Defendants touted Abstral's revenues (bullets a-e) and Galena's "long-term prospects" (bullet a; *see* bullet b (touting "long-term growth")) and attributed that revenue to "Galena's commercial business within the oncology space" (bullet c; *see also* bullet a (touting "enhancing our relationships in the oncology community"), to prescriptions for "oncology" (bullets b and c; *see also* bullet e (discussing the "increase in the number of Abstral prescriptions")), and to the purported fact that "providers have become more comfortable prescribing Abstral for their breakthrough <u>cancer pain patients</u>" (bullet c), they failed to disclose that (1) the touted financial results were achieved through Galena's illegal promotion of Abstral for off-label purposes (*i.e.,* non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral (including kickbacks for prescriptions that were known to be off-label); (2) Galena's net sales and revenues were reliant on illegal non-medical prescriptions of Abstral by at least two pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks and manipulate Galena's stock price; and (3) for these reasons, Abstral's

revenues were not sustainable, particularly in light of the government's increasing oversight of fentanyl prescriptions. Defendants misled investors that the Company's Abstral sales were sustainable through legitimate sales practices and promotions to physicians prescribing for on-label indications and/or actual medical need.

137. Under the "Risk Factors" section of the Form 10-K Galena further disclosed:

> In addition, our product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. ***In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians.*** The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.
>
> ... ***If we are not able to achieve and maintain regulatory compliance***, we may not be permitted to market our products, which would adversely affect our ability to generate revenue and achieve or maintain profitability.
>
> [Emphasis added.]

138. These "Risk Factors" statements were materially misleading. While Defendants acknowledged that promoting a drug for off-label purposes is illegal and could adversely affect revenue, they failed to disclose that Galena was then actively promoting Abstral for non-cancer (off-label) pain and had even paid illegal kickbacks for off-label prescriptions, including more than $97,000 in "rebates" to Drs. Ruan and Couch for their Abstral prescriptions written to non-cancer patients. Defendants' statement that "***[i]f*** we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products, which would adversely affect our ability to generate revenue and achieve or maintain profitability" was materially misleading because Defendants knew full well Galena was not in compliance with the applicable regulations by virtue of the fact that: (1) Galena, including its highest executives, had paid illegal kickbacks to Abstral prescribers (*e.g.*, Galena's RELIEF program, rebate program, and paid advisory positions), including kickbacks for prescriptions that were known to be off-label; and (2) Galena, at the direction of its

highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral.

5. May 7, 2015 Statements

139. On May 7, 2015, the Company announced its financial results for the first quarter ended March 31, 2015 and, in doing so, issued several materially false or misleading statements:

a) "***Net revenue was $2.8 million in the first quarter of 2015, a 28% increase compared to $2.2 million for the same period a year ago***…. Dr. Schwartz concluded, '***[O]n the commercial front, Abstral sales remain on target, <u>our oncology presence continues to grow</u>, and we reiterate our full year guidance of $15-$18 million for 2015***. Additionally, we are now preparing to launch Zuplenz in July, adding a second, supportive care commercial product to our oncology-focused sales portfolio. In total, ***we have established a strong foundation with our development programs supported by our commercial franchise***, and we remain committed to the growth of our company.'" (Galena's May 7, 2015 press release; *see also* Form 10-Q filed May 7, 2015, signed by Schwartz and Dunlap).

b) [Schwartz:] "***In addition to the development team's accomplishments, our commercial team recorded its second-best quarter of net revenue in the best back-to-back month since Abstral's product launch. Most importantly, we continued our increased penetration within the <u>oncology space</u>*** as we head into the launch of our second commercial oncology supportive care product, Zuplenz." (Earnings conference call, with Defendants Schwartz, Dunlap, Lento, and Bernarda participating).

c) [Lento:] "Thank you, Gavin, and good afternoon, everyone. ***As we shared with today's earnings release and as shown on slide number 11, we reported actual net revenue of $2.8 million for the first quarter of 2015, our second-highest quarter of net revenues since our relaunch of Abstral in 2013. In addition, the overall trend line as measured by end-user <u>product demand continues to grow</u> with March representing one of our best months to date.*** Equally important, our gross to net deduction also improved this quarter, from 63% in Q4 2014 to 65% in Q1 2015. ***One month into the second quarter, our performance metrics indicate a very strong month for Abstral in April as measured by customer demand***, but please remember that this is not a direct correlation to our net revenue, which is recorded based on ex-factory sales.

We continue to focus on refining Abstral's prescription fulfillment process as depicted on slide number 12. As a reminder, Abstral is an indicator for the treatment of breakthrough <u>cancer pain</u> in opioid tolerant adult <u>cancer patients</u>.

***

Our current market share in the branded turf market remains steady at around 5% of total prescriptions on a monthly basis measured by Wolters Kluwer. ***While our salesforce continues to call on pain specialists <u>who are treating a large number of cancer patients</u>, our long-term strategy is <u>to develop lasting relationships with medical oncologists, radiation oncologists, and palliative care specialists</u> since we believe this represents the most stable market, the best potential for Abstral, and <u>meets the goals as an oncology-focused organization</u>.***" (Earnings conference call, with Defendants Schwartz, Dunlap, Lento, and Bernarda participating).

d) [Dunlap:] "Thank you, Chris, and good afternoon, everyone. I'll start with our P&L shown on slide 22. ***Net revenue from the sale of Abstral for the first quarter of 2015 was $2.8 million which compares to $2.2 million for the same quarter last year. Based on our historical trends thus far as well as very positive things trends we have seen in the last part of Q1 and into Q2, we are pleased with the direction of our sales trends and remain confident in our 2015 net revenue guidance of $15 million to $18 million***." (Earnings conference call, with Defendants Schwartz, Dunlap, Lento, and Bernarda participating).

[Emphasis added.]

140. Defendants' May 7, 2015 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading. While Defendants touted Abstral's revenues (bullets a, c, and d) and attributed that revenue to prescriptions for "oncology" (bullets a and b) and Abstral's sales to "medical oncologists, radiation oncologists, and palliative care specialists" or "pain specialists who are treating a large number of cancer patients" (bullet c), they failed to disclose that (1) the touted financial results were achieved through Galena's illegal promotion of Abstral for off-label purposes (*i.e.*, non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral (including kickbacks for prescriptions that were known to be off-label); (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral written not for legitimate medical purposes by at least two pain doctors who made up ***30% of all Abstral*** sales in the country and who were overprescribing Abstral in an attempt to earn kickbacks and manipulate Galena's stock price; and (3) for these reasons, Abstral's revenues were not sustainable, particularly in light of the government's increasing oversight of fentanyl prescriptions. Defendants' statements were further rendered materially misleading because they failed to disclose that these illegal promotions and off-label

prescriptions were what was causing the positive "sales trends" (bulled d) and increasing "customer demand" (bullet c) represented by Defendants. Defendants misled investors that the Company's Abstral sales were sustainable through legitimate sales practices and promotions to physicians prescribing for on-label indications and/or actual medical need.

141. On the same day, May 7, 2015, the Company filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendants Schwartz and Dunlap, and reaffirmed the Company's financial results announced in the press release issued on the same day.

142. Under the "Risk Factors" section of the Form 10-Q Galena further disclosed:

> In addition, our product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. ***In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians.*** The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.
>
> … ***If we are not able to achieve and maintain regulatory compliance***, we may not be permitted to market our products, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

[Emphasis added.]

143. These "Risk Factors" statements were materially misleading. While Defendants acknowledged that promoting a drug for off-label purposes was illegal and could adversely affect revenue, they failed to disclose that Galena was then actively promoting Abstral for non-cancer (off-label) pain and had even paid more than $97,000 in "rebates" for off-label prescriptions. Defendants' statement that "***[i]f*** we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products, which would adversely affect our ability to generate revenue and achieve or maintain profitability" was materially misleading because Defendants knew full well Galena was not in compliance with the applicable regulations by virtue of the fact that: (1) Galena,

including its highest executives, had paid illegal kickbacks to Abstral prescribers (e.g., Galena's RELIEF program, rebate program, and paid advisory positions), including kickbacks for prescriptions that were known to be off-label; and (2) Galena, at the direction of its highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral.

144. On May 20, 2015, ***Dr. Ruan and Couch's offices were raided*** by law enforcement, and their PPSA clinics and C&R Pharmacy ***<u>were shut down</u>***.

6. August 6, 2015 Statements

145. On August 6, 2015, Galena announced its financial results for the second quarter ended June 30, 2015 and, in doing so, issued a series of materially false or misleading statements:

a) Galena's press release, dated August 6, 2015, reported "***[n]et revenue was $3.4 million in the second quarter of 2015, a 48% increase compared to $2.3 million reported for the same period in 2014. Net revenue was $6.1 million in the first half of 2015, a 36% increase compared to $4.5 million reported for the same period in 2014***." Galena's press release also quoted Defendant Schwartz as stating: "'***And, today we reported improved Abstral sales quarter over quarter resulting in our strongest net revenue quarter to date. Based on current projections, we anticipate that we will come in closer to the lower end of our guidance range, at around $15 million for the year***.'" (Press Release issued August 6, 2015; *see also* Form 10-Q filed August 6, 2015, signed by Schwartz and Dunlap).

b) [Schwartz:] "***As we noted in our press release, we recorded net revenue of $6.1 million thus far this year from Abstral sales, and are very proud of our Commercial team for bringing in our highest quarterly net revenue to date of $3.4 million in Q2.***

Abstral is part of the transmucosal immediate release fentanyl, or TIRF, market that is very competitive, and has received a great deal of press this year. ***As Chris will go into in more detail, <u>our metrics for Abstral are trending in the right direction</u>, although our sales growth has fluctuated quarter-over-quarter based on field demand and wholesaler inventory levels.***

Because of the ongoing market dynamics, the quarterly variability around our reported sales, and the fact that we've just launched Zuplenz and have yet to recognize revenue to date for that product, it is appropriate for us to guide to a lower end of our range with the expected full-year revenue of around $15

million for both products. We continue to work to make our Commercial business accretive, and we are evaluating our commercial options and strategy to achieve long-term profitability and maximize the value of our commercial assets, with a goal of building shareholder value." (Earnings conference call on August 6, 2015 with Defendants Schwartz, Dunlap, Lento, and Bernarda participating).

c) [Lento:] "Thank you, Gavin. And good afternoon, everyone. I'll start my discussion with Abstral. As a reminder, Abstral is indicated for the treatment of breakthrough cancer pain in opioid-tolerant adult cancer patients, and falls under the TIRF REMS Access program. ***I am pleased to report Abstral net revenue of $3.4 million for the second quarter of 2015 -- our highest net revenue quarter since launch.***

This is a result of our team adding new prescribers and the continued adoption of our Galena patient services, or GPS program. On slide 16, <u>you can see this trajectory</u>. In addition, our gross to net deduction improved to 77% this quarter compared to 65% in Q1 2015.

***

As we have mentioned on previous calls, the growth of Abstral will continue to fluctuate quarter-over-quarter. But as you have seen, <u>the underlying metrics are all trending upwards</u>.

***

Our account management team has secured product availability with all of our distribution partners, assuring product access for all healthcare providers ***<u>and their appropriate patients.</u>***

***

In summary, ***<u>our Abstral business is growing</u>***, and we are enthusiastic about selling Zuplenz where our very early reception of the product has been positive." (Earnings conference call on August 6, 2015 with Defendants Schwartz, Dunlap, Lento, and Bernarda participating).

[Emphasis added.]

146. Defendants' August 6, 2015 statements (in Galena's press release, Form 10-Q, and earnings call) were materially false or misleading because they falsely asserted that Abstral's "underlying metrics are all trending upwards" (bullet c) or in the "right direction" (bullet b) and that "our Abstral business is growing" (bullet c), when the exact opposite was true. In truth, the two doctors responsible for ***30%*** of the Company's Abstral prescriptions had been arrested and their

businesses shut down in May 2015, which resulted in "significantly" reduced Abstral sales (as David Corin, Galena's National Sales Director, testified). Moreover, while Defendants attributed the disappointing earnings to "ongoing market dynamics" (bullet b), this was materially misleading given that the actual reason for the lower earnings was that Galena had lost its two top Abstral prescribers because the doctors had been arrested for writing illegal prescriptions outside the usual course of professional practice and not for a legitimate medical purpose—illegal prescriptions induced by Defendants. Thus, Defendants' statements misled investors by failing to disclose that Abstral's revenues were not sustainable, certainly not at the reported level.

147. On the same day, August 6, 2015, the Company filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendants Schwartz and Dunlap, and reaffirmed the Company's financial results announced in the press release issued on the same day. Under the "Risk Factors" section of the Form 10-Q Galena further disclosed:

> ***We may be unable to achieve profitability with our commercial operations in a timely manner, and may have to make changes to our commercial strategy to maximize the value of our commercial assets to our shareholders.***
>
> We launched Abstral in the fourth quarter of 2013, and launched Zuplenz on July 29, 2015. As of June 30, 2015, Abstral has not achieved profitability as a product line, and there is no assurance that it will achieve profitability within the period of time outlined by management in setting our commercial strategy. Also, there is no assurance that we will be successful launching Zuplenz, or that Zuplenz will reach profitability as a product line in timely manner, if ever.
>
> Management may determine that a change to our commercial strategy is necessary to address the lack of profitability of the commercial products. Such potential strategic changes include, but are not limited to, increased investment in our commercial operations, significant expansion or reduction to our sale force, acquisition of additional commercial products, or partial or full divesture of our commercial products and operations. Any such significant change to our commercial strategy could materially affect the amounts of revenue we generate in future periods, the extent and timing of future costs incurred, and could result in changes to our financial results that are materially different than those realized historically.

148. On the news of Galena's disappointing earnings and reduced revenue guidance, the Company's stock price fell $0.12, or 7.4%, from its closing price of $1.63 on August 6, 2015 to close

at $1.51 on August 7, 2015. The August 6, 2015 disclosures of lower earnings and expectations partially revealed the risks concealed by Defendants' misstatements. In particular, these disclosures revealed the materialized risk that Abstral sales would drop off when the illegal promotion by Galena and illegal prescriptions for Abstral written by Galena's top two prescribers could not be sustained. Indeed, this is exactly what happened when (although not disclosed by Galena) law enforcement closed down Drs. Ruan and Couch's practices, clinics, and pharmacy in late May 2015. This disclosure, however, was only partially corrective. Galena's stock price would have dropped more if the full truth had been revealed. Indeed, the August 6, 2015 disclosures were both actionably misleading and partially corrective.

B. Defendants' Materially Misleading Statements Regarding the Discontinuation of its Commercial Operations, Galena's Exposure to Liability, and Government Investigations

1. November 9, 2015 Statements

149. On November 9, 2015, Galena announced in a press release that it had decided to divest its commercial business, which included Abstral. As such, the Company's commercial business activities were classified as "discontinued operations," and Galena stated that it anticipated exiting the commercial business by the end of the first quarter of 2016. In making this announcement, Galena made the following materially false or misleading statements, quoting Schwartz:

> "Dr. Schwartz continued, '***When I assumed the position of President and CEO of Galena, I, along with our executive team, began a careful examination of our operations and assets to determine the optimal strategy for Galena that would enable the greatest opportunity for growth, while maximizing shareholder value. As a result of this analysis and review by our Board of Directors, we have concluded that it is in the best interest of our patients, our shareholders, and the long-term success of our company to focus our energy and resources exclusively on our clinical development programs.*** Since acquiring the products we have significantly grown the sales of Abstral and successfully launched Zuplenz, and I believe that each has strong commercial potential and offers significant benefits to their respective patient populations. ***However, the foundation of Galena has always been our cancer immunotherapy programs, which are now rapidly advancing towards several key inflection points. Therefore, we believe it is important for Galena to focus on our core expertise and the successful advancement of our late and mid stage clinical***

> ***pipeline.*** We appreciate the dedication and hard work of the commercial team as we transition out of the commercial business and are extremely grateful for all of their efforts.'
>
> Dr. Schwartz concluded, 'For both patients and shareholders of Galena, there is a much greater opportunity to generate value if we dedicate all of our resources to our clinical programs, and we are eager to move the company in this new direction….'"
>
> [Emphasis added.]

150. Defendants' November 9, 2015 statements (in Galena's press release) misled investors as to the true reasons for Galena's discontinuance of commercial operations and consequently misled investors as to Galena's serious exposure to civil and criminal liability. Galena's discontinuance of commercial operations was not the result of "a careful examination of our operations and assets to determine the optimal strategy for Galena" that began "[w]hen [Schwartz] assumed the position of President and CEO of Galena" in August 2014, as Schwartz falsely proclaimed. Rather, the central reason that Galena discontinued its commercial operations was that its two main prescribers had been arrested for running a "pill mill" and their practices had been shut down, which so severely curtailed Galena's Abstral business that the entire commercial operations could no longer be sustained. Thus, Defendants concealed the risks Galena was exposed to from its discontinued commercial operations in that Defendants failed to disclose: (1) that Galena, including its highest executives, had paid illegal kickbacks to Abstral prescribers (*e.g.*, Galena's RELIEF program, rebate program, and paid advisory positions); (2) that Galena, at the direction of its highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral and providing kickbacks for prescriptions that were known to be off-label; (3) that Galena and its executive officers encouraged doctors, including Drs. Ruan and Couch, to excessively prescribe Abstral for non-medical purposes; (4) that Galena knew Drs. Ruan, Couch, and Rho owned shares of Galena stock and that they were looking to manipulate the stock; (5) that the Company violated various federal statutes—including the federal Anti-Kickback Statute and the

Sunshine Act—in connection with its promotion and sales of Abstral, or the activities underlying those violations; and (6) that, as a result of the foregoing, the Company was exposed to civil and criminal liability.

151. On the same day, November 9, 2015, the Company filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendants Schwartz and Dunlap, and reaffirmed the Company's financial results announced in the press release issued on the same day. Galena also disclosed that the Company had "assessed the commercial business net asset group for impairment pursuant to FASB Topic 360, . . . determinin[ed] that the carrying value exceeds the fair value of the assets, [and] therefore has recorded a $8.1 million impairment charge as of September 30, 2015."

152. On the November 9, 2015 news, the price of Galena common stock fell $0.19 per share, or 11%, to close at $1.53 per share on November 10, 2015. The November 9, 2015 disclosures of the discontinuation of Galena's commercial business further partially revealed even more of the risks concealed by Defendants' misstatements. That is, these disclosures revealed the risk concealed by Defendants that the commercial operations of Galena could not be sustained without the illegal promotion by Galena and illegal prescriptions for Abstral written by Galena's top two prescribers. These disclosures revealed the severity of those risks in that the sales drop off (more than 30% of the Abstral business lost when Drs. Ruan and Couch were forced to shut down) was so pronounced that Galena's entire commercial business had to be discontinued. But the disclosure of these materialized risks was only partially corrective as to Defendants' materially false and misleading statements because they did not disclose the underlying causes of the risks that materialized and thus concealed Galena's potential civil and criminal exposure. The price of the stock would have dropped even more if the full truth had been revealed. Indeed, the November 9, 2015 disclosures were both actionably misleading and partially corrective.

153. On November 20, 2015, the Company announced that it had sold its Abstral product to a private company in a deal valued at up to $12 million, with $8 million cash up-front, and up to $4 million in additional cash upon the achievement of certain sales milestones, effective as of November 19, 2015.

154. Then, on December 11, 2015, the Company announced the departure of Defendant Dunlap, effective December 31, 2015:

> Mr. Ryan Dunlap, the current Chief Financial Officer (CFO) of the registrant, advised that he and his family will be unable to relocate to the Company's new headquarters' in San Ramon, California, and as a result he will leave the Company effective December 31, 2015.

155. On this news, the price of Galena common stock fell $0.07 per share, or 4.5%, to close at $1.49 per share on December 11, 2015.

2. December 22, 2015 Statements

156. On December 22, 2015, the Company announced in a press release the receipt of a federal subpoena in connection with its sales of Abstral. In the press release, Defendants made the following misleading statements:

> On December 16, 2015, Galena Biopharma, Inc. ("Galena") received a subpoena from the U.S. Attorney's Office for the District of New Jersey. The subpoena requests the production of a broad range of documents pertaining to marketing and promotional practices related to the product ABSTRAL® (fentanyl) Sublingual Tablets. Galena intends to cooperate with the government's investigation. Galena can make no assurances as to the time or resources that will need to be devoted to this inquiry or its final outcome, or the impact, if any, of this inquiry or any proceedings on Galena's business, financial condition, results of operations and cash flows.

157. Galena's broad statements that the Company had "received a subpoena from the U.S. Attorney's Office for the District of New Jersey" and that such subpoena requested documents related to Galena's "marketing and promotional practices" with respect to Abstral were materially misleading in that they concealed the level of risk to which the Company was exposed from the promotional practices of Galena's discontinued commercial operations. Indeed, Galena failed to

disclose that its two main prescribers had been arrested for running a "pill mill" and their practices shut down. Defendants also omitted the facts underlying Galena's promotional activities or risks therefrom, including: (1) that Galena, including its highest executives, had paid illegal kickbacks to Abstral prescribers (*e.g.*, Galena's RELIEF program, rebate program, and paid advisory positions); (2) that Galena, at the direction of its highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral and providing kickbacks for prescriptions that were known to be off-label; (3) that Galena and its executive officers encouraged doctors, including Drs. Ruan and Couch, to excessively prescribe Abstral for non-medical purposes; (4) that Galena knew Drs. Ruan, Couch, and Rho owned shares of Galena stock and that they were looking to manipulate the stock; (5) that the Company violated various federal statutes—including the federal Anti-Kickback Statute and the Sunshine Act—in connection with its promotion and sale of Abstral, or the activities underlying those violations; and (6) that, as a result of the foregoing, the Company was exposed to civil and criminal liability.

158. On this news, the price of Galena common stock fell $0.06 per share, or 3.6%, to close at $1.57 per share on December 23, 2015. But, the December 22, 2015 disclosures were only partially corrective as demonstrated by the muted reaction of the market. The price of the stock would have dropped more if the full truth had been revealed. Indeed, the December 22, 2015 disclosures were both actionably misleading and partially corrective.

3. March 10, 2016 Statements

159. On March 10, 2016, the Company filed its amended annual report for the year ended December 15, 2015 on Form 10-K/A with the SEC. The 10-K/A was signed by Defendant Schwartz. In the "Risk Factors" section, the Company disclosed:

> ***We are subject to U.S. federal and state health care fraud and abuse and false claims laws and regulations, and we recently have been subpoenaed in connection***

> ***with marketing and promotional practices related to Abstral. Prosecutions under such laws have increased in recent years and we may become subject to such prosecutions or related litigation under these laws. <u>If we have not fully complied with such laws</u>, we could face substantial penalties.***
>
> Our former commercial operations and development programs are subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal False Claims Act, federal Anti-Kickback Statute, and the federal Sunshine Act.
>
> ***A federal investigation of two of the high-prescribing physicians for Abstral has resulted in the criminal prosecution of the two physicians for alleged violations of the federal False Claims Act and other federal statutes. The criminal trial is set for some time in 2016. We have received a trial subpoena for documents in connection with that investigation*** and we have been in contact with the U.S. Attorney's Office for the Southern District of Alabama, which is handling the criminal trial, and are cooperating in the production of documents. We are not a target or subject of that investigation. There also have been federal and state investigations of a company that has a product that competes with Abstral in the same therapeutic class, and ***we have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices. On December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office in District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral.*** We have been in contact with the U.S. Attorney's Office for the District of New Jersey and are cooperating in the production of the requested documents. We are unable to predict whether we could become subject to legal or administrative actions as a result of these matters, or the impact of such matters. If we are found to be in violation of the False Claims Act, Anti-Kickback Statute, Patient Protection and Affordable Care Act, or any other applicable state or any federal fraud and abuse laws, we may be subject to penalties, such as civil and criminal penalties, damages, fines, or an administrative action of exclusion from government health care reimbursement programs. We can make no assurances as to the time or resources that will need to be devoted to these matters or their outcome, or the impact, if any, that these matters or any resulting legal or administrative proceedings may have on our business or financial condition.
>
> [Emphasis in bold and italics in original.]

160. Defendants' broad statements, including that "we have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices" and that the Company had "received a subpoena from the U.S. Attorney's Office for the District of New Jersey" that requested documents related to Galena's "marketing and promotional practices" with respect to Abstral, were materially incomplete and misleading because they concealed the level of risk to which the Company was exposed from the promotional practices of Galena's discontinued commercial

operations. Specifically, Defendants omitted the facts underlying Galena's promotional activities or risks therefrom, including: (1) that Galena, including its highest executives, had paid illegal kickbacks to Abstral prescribers (*e.g.*, Galena's RELIEF program, rebate program, and paid advisory positions); (2) that Galena, at the direction of its highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral and providing kickbacks for prescriptions that were known to be off-label; (3) that Galena and its executive officers encouraged doctors, including Drs. Ruan and Couch, to excessively prescribe Abstral for non-medical purposes; (4) that the Company violated various federal statutes—including the federal Anti-Kickback Statute—in connection with its promotion and sales of Abstral, or the activities underlying those violations; and (5) that, as a result of the foregoing, the Company was exposed to civil and criminal liability. Defendants' statement that "***[i]f*** we have not fully complied with such laws, we could face substantial penalties" was materially misleading because Defendants knew full well Galena had not complied with the applicable regulations by virtue of the fact that: (1) Galena, including its highest executives, had paid illegal kickbacks to Abstral prescribers (*e.g*., Galena's RELIEF program, rebate program, and paid advisory positions), including kickbacks for prescriptions that were known to be off-label; and (2) Galena, at the direction of its highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral.

161. On this news, the price of Galena common stock fell $0.03 per share, or 3.3%, to close at $0.86 per share on March 11, 2016. But, the March 10, 2016 disclosures were only partially corrective as demonstrated by the muted reaction of the market. The price of the stock would have dropped more if the full truth had been revealed. Indeed, the March 10, 2016 disclosures were both actionably misleading and partially corrective.

4. May 10, 2016 Statements

162. Then, on May 10, 2016, the Company filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendant Schwartz. Therein, the Company stated:

> ***We are subject to U.S. federal and state health care fraud and abuse and false claims laws and regulations, and we recently have been subpoenaed in connection with marketing and promotional practices related to Abstral. Prosecutions under such laws have increased in recent years and we may become subject to such prosecutions or related litigation under these laws. <u>If we have not fully complied with such laws</u>, we could face substantial penalties.*** [Emphasis in bold and italics in original.]
>
> Our former commercial operations and development programs are subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal False Claims Act, federal Anti-Kickback Statute, and the federal Sunshine Act.
>
> A federal investigation of two of the high-prescribing physicians for Abstral has resulted in the criminal prosecution of the two physicians for alleged violations of the federal False Claims Act and other federal statutes. The criminal trial is set for some time in 2016. We have received a trial subpoena for documents in connection with that investigation and we have been in contact with the U.S. Attorney's Office for the Southern District of Alabama, which is handling the criminal trial, and are cooperating in the production of documents. ***On April 28, 2016, a second superseding indictment was filed in the criminal case, which added additional information about the defendant physicians and <u>provided information regarding the facts and circumstances involving a rebate agreement between the Company and the defendant physicians' pharmacy as well as their ownership of our stock</u>.*** To our knowledge, we are a not target or subject of that investigation. There also have been federal and state investigations of a company that has a product that competes with Abstral in the same therapeutic class, and ***we have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices.*** On December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office in District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral. We have been in contact with the U.S. Attorney's Office for the District of New Jersey and are cooperating in the production of the requested documents. We are unable to predict whether we could become subject to legal or administrative actions as a result of these matters, or the impact of such matters. If we are found to be in violation of the False Claims Act, Anti-Kickback Statute, Patient Protection and Affordable Care Act, or any other applicable state or any federal fraud and abuse laws, we may be subject to penalties, such as civil and criminal penalties, damages, fines, or an administrative action of exclusion from government health care reimbursement programs. We can make no assurances as to the time or resources that will need to be devoted to these matters or their outcome, or the impact, if any, that these matters or any resulting legal or administrative proceedings may have on our business or financial condition.

> The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal government. …
>
> The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. … An alleged violation of the Anti-Kickback Statute may be used as a predicate offense to establish liability pursuant to other federal laws and regulations such as the federal False Claims Act. …
>
> The federal Patient Protection and Affordable Care Act includes provisions expanding the ability of certain relators to bring actions that would have been dismissed under prior law. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. … ***The federal Patient Protection and Affordable Care Act includes provisions known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 to the Centers for Medicare and Medicaid Services for subsequent public disclosures. Manufacturers must also disclose investment interests held by physicians and their family members.***
>
> [Emphasis added.]

163. Defendants' May 10, 2016 statement, "If we have not fully complied with such laws, we could face substantial penalties" was materially misleading in that Defendants knew full well Galena had not complied with "U.S. federal and state health care fraud and abuse and false claims laws and regulations." Defendants' statement: "On April 28, 2016, a second superseding indictment was filed in the criminal case, which added additional information about the defendant physicians and provided information regarding the facts and circumstances involving a rebate agreement between the Company and the defendant physicians' pharmacy as well as their ownership of our stock," was also materially incomplete and misleading. Specifically, this statement failed to disclose that the "rebate agreement" was in fact a kickback agreement (whereby doctors were illegally paid for writing off-label prescriptions of Abstral). Additionally, Defendants' broad statements that "we

have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices" and that the Company had "received a subpoena from the U.S. Attorney's Office for the District of New Jersey" that requested documents related to Galena's "marketing and promotional practices" with respect to Abstral were materially incomplete and misleading. These statements failed to disclose the following material information: (1) that Galena, including its highest executives, had paid illegal kickbacks to Abstral prescribers (*e.g.*, Galena's RELIEF program, rebate program, and paid advisory positions); (2) that Galena, at the direction of its highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral and providing kickbacks for prescriptions that were known to be off-label; (3) that Galena and its executive officers encouraged doctors, including Drs. Ruan and Couch, to excessively prescribe Abstral for non-medical purposes; (4) that the Company violated various federal statutes—including the federal Anti-Kickback Statute—in connection with its promotion and sales of Abstral, or the activities underlying those violations; and (5) that, as a result of the foregoing, the Company was exposed to civil and criminal liability. Moreover, Defendants' discussion of the Sunshine Act and its requirement that drug manufacturers must "disclose investment interests held by physicians and their family members" was also materially misleading since it did not disclose: (1) that Galena had always known, but had consistently failed to disclose, that Drs. Ruan, Couch, and Rho owned shares of Galena stock (and were looking to manipulate the stock), and (2) that Galena had violated the Sunshine Act by previously failing to disclose these doctors' stock ownership.

164. On the news that "a second superseding indictment was filed in the criminal case, which added additional information about the defendant physicians and provided information regarding the facts and circumstances involving a rebate agreement between the Company and the defendant physicians' pharmacy as well as their ownership of our stock," Galena's stock price fell

$0.10, or 7.2%, to close at $1.38 on May 11, 2016. But, the May 10, 2016 disclosures were only partially corrective. The price of the stock would have dropped more if the full truth had been revealed, as indicated by the 22.4% drop in Galena's stock price with the corrective disclosure on January 31, 2017 (the last day of the Class Period). Indeed, the May 10, 2016 disclosures were both actionably misleading and partially corrective.

5. August 9, 2016 and November 9, 2016 Statements

165. On August 9, 2016, the Company filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendant Schwartz.

166. In the "Risk Factors" section of the Form 10-Q Defendants disclosed:

> ***We are, and in the future may be, subject to legal or administrative actions that could adversely affect our financial condition and our business.*** [emphasis in original]
>
> ***
>
> A federal investigation of two of the high-prescribing physicians for Abstral has resulted in the criminal prosecution of the two physicians for alleged violations of the federal False Claims Act and other federal statutes. The criminal trial is set for October 2016. We have received a trial subpoena for documents in connection with that investigation and we have been in contact with the U.S. Attorney's Office for the Southern District of Alabama, which is handling the criminal trial, and are cooperating in the production of documents. On April 28, 2016, a second superseding indictment was filed in the criminal case, which added additional information about the defendant physicians and provided information regarding the facts and circumstances involving a rebate agreement between the Company and the defendant physicians' pharmacy as well as their ownership of our stock. ***Certain former employees have received trial subpoenas to appear at the trial and provide oral testimony.*** We have agreed to reimburse those former employees' attorney's fees. To our knowledge, we are not a target or subject of that investigation.
>
> ***There also have been federal and state investigations of a company that has a product that competes with Abstral in the same therapeutic class, and we have learned that the FDA and other governmental agencies are investigating our Abstral promotion practices.*** On December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office in District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral. We have been in contact with the U.S. Attorney's Office for the District of New Jersey and are cooperating in the production of the requested documents. We are unable to predict whether we could become subject to legal or administrative actions as a result of these matters, or the impact of such matters.

> If we are found to be in violation of the False Claims Act, Anti-Kickback Statute, Patient Protection and Affordable Care Act, or any other applicable state or any federal fraud and abuse laws, we may be subject to penalties, such as civil and criminal penalties, damages, fines, or an administrative action of exclusion from government health care reimbursement programs. We can make no assurances as to the time or resources that will need to be devoted to these matters or their outcome, or the impact, if any, that these matters or any resulting legal or administrative proceedings may have on our business or financial condition.
>
> [Emphasis added.]

167. These risk disclosures, including the broad statement that "we have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices," were similarly materially incomplete and misleading to the earlier ones. Defendants failed to disclose the underlying facts or risks therefrom, including: (1) that the investigation was targeting Galena's highest executives, including its CEO Defendant Schwartz (as opposed to targeting rogue lower-level salesman); (2) that Galena, including its highest executives, had paid illegal kickbacks to Abstral prescribers (*e.g.*, Galena's RELIEF program, rebate program, and paid advisory positions); (3) that Galena, at the direction of its highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral and providing kickbacks for prescriptions that were known to be off-label; (4) that Galena and its executive officers encouraged doctors, including Drs. Ruan and Couch, to excessively prescribe Abstral for non-medical purposes; (5) that Galena had always known, but consistently failed to disclose, that Drs. Ruan, Couch, and Rho owned shares of Galena stock (and were looking to manipulate the stock); (6) that the Company violated various federal statutes—including the federal Anti-Kickback Statute and the Sunshine Act—in connection with its promotion and sales of Abstral, or the activities underlying those violations; and (7) that, as a result of the foregoing, the Company was exposed to civil and criminal liability.

168. On November 9, 2016, the Company filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendant Schwartz. The Company made the same disclosures

concerning ongoing investigations and prosecutions that were made in the second quarter 2016 Form 10-Q filed on August 9, 2016. Likewise, Galena's November 9, 2016 statements were materially misleading for the reasons discussed in the above paragraph.

6. January 9, 2017 Statements

169. On January 9, 2017, the Company filed a Form 8-K with the SEC, which updated Galena's risk disclosures for the year ended December 31, 2015 to disclose that Galena was under criminal investigation by the United States DOJ. The Company disclosed:

> ***Abstral Investigation***
>
> As previously disclosed, on December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office for the District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral, the commercial product we sold in the fourth quarter of 2015. ***We have been in contact with the U.S. Attorney's Office for the District of New Jersey and Department of Justice, and we have come [to] understand that the investigation being undertaken by the U.S. Attorney's Office for the District of New Jersey and Department of Justice is a criminal investigation in addition to a civil investigation that could ultimately involve the Company as well as one or more current and/or former employees.*** Pursuant to the Company's charter, we are currently reimbursing any former and current employees' attorney's fees with respect to the investigation. We are cooperating with the civil and criminal investigation, and through our outside counsel we have recently begun preliminary discussions with the government aimed at the ultimate resolution of the investigation regarding the Company.
>
> **Update of Risk Factor**
>
> In light of the disclosure above regarding the Abstral Investigation, the Company is updating the risk factor that appear under the heading "Risks Relating to Our Former Commercial Operations" in all quarterly and annual reports filed under the Securities Exchange Act of 1934, as amended, subsequent to the Company's Annual Report on Form 10-K for the Annual Period Ended December 31, 2015. The following risk factor shall be incorporated by reference into all of the Company's registration statements under the Securities Act of 1933, as amended. Investors in our common stock should carefully consider this risk factor below as well as all other risk factors disclosed in our most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and the other information disclosed by us before making an investment decision.
>
> **Risks Relating to Our Former Commercial Operations**
>
> ***We have come to understand that the investigation being undertaken by the U.S. Attorney's Office for the District of New Jersey and Department of Justice is a***

criminal investigation in addition to a civil investigation that could ultimately involve the company as well as one or more current and/or former employees.

[Emphasis added.]

170. Although Defendants disclosed the criminal investigation relating to the Company's discontinued operations, Defendants' January 9, 2017 statement that "[w]e have come to understand that the investigation being undertaken by the U.S. Attorney's Office for the District of New Jersey and Department of Justice is a criminal investigation in addition to a civil investigation that could ultimately involve the company as well as one or more current and/or former employees," was materially misleading in that Defendants never disclosed: (1) the investigation was targeting Galena's highest executives, including its CEO Defendant Schwartz (as opposed to targeting rogue lower-level salesman); (2) that Galena, including its highest executives, had paid illegal kickbacks to Abstral prescribers (*e.g.*, Galena's RELIEF program, rebate program, and paid advisory positions); (3) that Galena, at the direction of its highest executives, consistently illegally promoted Abstral for off-label purposes, including making sales calls and trips to pain management doctors who Galena knew were writing off-label prescriptions of Abstral and providing kickbacks for prescriptions that were known to be off-label; (4) that Galena and its executive officers encouraged doctors, including Drs. Ruan and Couch, to excessively prescribe Abstral for non-medical purposes; (5) that Galena had always known, but consistently failed to disclose, that Drs. Ruan, Couch, and Rho owned shares of Galena stock (and were looking to manipulate the stock); (6) that the Company violated various federal statutes—including the federal Anti-Kickback Statute and the Sunshine Act—in connection with its promotion and sales of Abstral, or the activities underlying those violations; and (7) that, as a result of the foregoing, the Company was exposed to far greater civil and criminal liability than suggested by the January 9, 2017 Form 8-K.

171. On this news, the price of Galena common stock fell $0.04 per share, or 1.9%, to close at $2.03 per share on January 9, 2017. The disclosures were incomplete and only partially corrective

as evidenced by the fact that the market barely moved as the result of these disclosures. The price of Galena stock would have dropped way more had the full truth been revealed. Indeed, the January 9, 2017 disclosures were both actionably misleading and partially corrective.

C. Defendants' Materially False and Misleading Statements Regarding Known Trends and Uncertainties Galena Reasonably Expected to Have a Material Unfavorable Impact on Results of Operations

172. SEC Regulation S-K (and SEC Forms 10-K and 10-Q) require disclosure of information, including information required to be disclosed under Items 303(a) and (b) of Regulation S-K (17 C.F.R. §229.303), in the non-financial-statement portions of annual reports filed on SEC Form 10-K and quarterly reports filed on SEC Form 10-Q under the Exchange Act. 17 C.F.R. §229.10. This information must be disclosed in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" ("MD&A") sections of SEC Forms 10-K and 10-Q.

173. For full fiscal years (*i.e.* annual statements on Form 10-K, Item 7), Item 303(a) requires the registrant to, among other things:

> (ii) Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.

174. Instruction 3 to paragraph 303(a) provides that "[t]he discussion and analysis shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition." 17 C.F.R. §229.303(a), Instruction 3. The SEC's interpretive release regarding Item 303 clarifies that the Regulation imposes a disclosure duty "where a trend, demand, commitment, event or uncertainty is both [1] presently known to management and [2] reasonably likely to have material effects on the registrant's financial condition or results of operations." Management's Discussion and Analysis of Financial Condition and Results of Operations, Securities

Act Release No. 6835, Exchange Act Release No. 26,831, Investment Company Act Release No. 16,961, 43 SEC Docket 1330 (May 18, 1989).

175. The SEC has explained that, without Item 303's required disclosures, a company's numerical financial statements and accompanying footnotes "may be insufficient for an investor to judge the quality of earnings and the likelihood that past performance is indicative of future performance." 54 Fed. Reg. at 22,428; *see id.* (discussion "give[s] the investor an opportunity to look at the company through the eyes of management"). The required disclosure is "[o]ne of the most important elements necessary to an understanding of a company's performance." 68 Fed. Reg. 75,061 (Dec. 29, 2003).

176. A reasonable investor knows that issuers file Forms 10-K and 10-Q "because Section 13(a) and SEC regulations require them." *Leidos, Inc. v. Indiana Public Retirement System,* 2017 WL 4004533 at *10 (U.S., 2017) (the "SEC Amicus Brief" or "SEC Amicus Br") (citing 15 U.S.C. 78m(a) ("shall file"); 17 C.F.R. 249.310(a) ("shall" use Form 10-K)); 17 C.F.R. 249.308(a) ("shall" use Form 10-Q). A reasonable investor also knows that issuers include an MD&A section disclosing known trends and uncertainties because Forms 10-K and 10-Q instruct and "require[] the issuer to include an MD&A section '[f]urnish[ing] the information required by Item 303,' SEC Form 10-K (Item 7); SEC Form 10-Q (Item 2), and because Item 303 requires an MD&A to disclose 'any' known trends or uncertainties that qualify[.]" Amicus Br. at *10. "A reasonable investor in turn would expect the MD&A section" of a Form 10-K or Form 10-Q "to disclose all the information that Item 303 requires, at least in the absence of language specifically disclaiming that implication." *Id.* "If…[an issuer] omitted facts that Item 303 required to be disclosed, [the issuer's] MD&A [is] the sort of misleading half-truth that may constitute actionable securities fraud if the other prerequisites to liability can be established." *Id.* "An incomplete MD&A is misleading because a reasonable investor knows that an issuer must include an MD&A section to comply with an SEC mandate (Item 303)

that requires disclosure of *all* the known trends and uncertainties that meet the regulatory ("reasonable expectation") threshold."[7] Amicus Br. *12. "In light of that mandate, a reasonable investor understands an MD&A as implicitly representing that no additional qualifying trends or uncertainties exist." *Id.*

177. "A reasonable investor, reading an MD&A in the applicable legal context, understands it to contain all of the information required by Item 303. An MD&A that discloses only some of the information Item 303 requires therefore is misleading." *Id.* at *8. Examples that help illustrate the point are set forth in the SEC Amicus Brief at *11:

> If SEC regulations required a Form 10-K to identify every pending lawsuit against the issuer in which the plaintiff sought more than $10 million in damages, and an issuer filed a Form 10-K listing ten such lawsuits, a reasonable investor would understand the filing as a representation that the list was exhaustive. *Cf.* 17 C.F.R. 229.103 (requiring disclosure of certain legal proceedings). If an additional suit seeking $20 million was actually pending, the filing would be misleading even though it did not explicitly deny the existence of the eleventh suit.
>
> Similarly, if SEC regulations required a Form 10-K to disclose any pending personal bankruptcy petitions filed by a director, and an issuer filed a Form 10-K that omitted that section or left it blank, a reasonable investor likewise would understand the filing to represent implicitly that no director had filed for bankruptcy. If one of the company's directors actually had, the Form 10-K would be misleading. Cf. *In re Ciro, Inc.*, Exchange Act Release No. 34,767, 57 SEC Docket 1893 (Sept. 30, 1994).
>
> The conclusion that such half-truths are misleading would leave open questions of materiality or scienter. If the undisclosed eleventh lawsuit sought $20 million in damages but was frivolous and immaterial under *Basic*, it would not be actionable under Section 10(b). The company's Form 10-K still would be misleading, however, because it would lead a reasonable investor to believe that the list of ten suits was exhaustive. If the issuer omitted the eleventh lawsuit through an innocent mistake, its lack of scienter likewise would prevent the imposition of liability under Section 10(b), but the form would still be misleading, because "whether a statement is 'misleading' depends on the perspective of a reasonable investor." *Omnicare*, 135 S. Ct. at 1327.

SEC Amicus Br. at *11-12.

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[7] The SEC's longstanding position is that a <u>material</u> omission under Item 303 is actionable under Rule 10b-5 as <u>both</u> (1) a violation of a statutory duty to disclose, and (2) <u>a misleading half-truth</u>. Amicus Br at *6-7, 22-23.

178. Defendants made the following materially misleading statements in the MD&A sections of Galena's Forms 10-K and 10-Q:

1. August 11, 2014 Form 10-Q Second Quarter 2014

179. On August 11, 2014, Galena filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendants Ahn and Dunlap, and reaffirmed the Company's financial results announced in the press release issued the same day.

180. In the MD&A section (Item 2)[8] of the Form 10-Q Galena disclosed:

> Our gross revenue is affected by the timing of customer orders, which timing sometimes results in quarter-to-quarter fluctuations in gross revenue. From time to time we have offered favorable pricing and extended payment terms to new wholesale distributor customers as an incentive to place initial Abstral orders. ***In the second quarter of 2014, we afforded such incentives to one of our principal customers with respect to an order from which we recognized approximately $1.5 million of gross revenue (ex-manufacturer), or approximately $0.9 million of net revenue. The timing and amount of this recent order could cause a corresponding reduction in orders from this customer, and in related revenue, in the third quarter of 2014.***
>
> ***In August 2014, Express Scripts Inc. (ESI), a major pharmacy benefits manager, made public their formulary exclusion list, which included Abstral and several of the most significant competing products, including the leading branded product in the market. The exclusion means that, effective on January 1, 2015, ESI will no longer purchase these excluded products***. Based on our preliminary assessment, we do not believe this formulary change will have a material, adverse effect on our Abstral customer base. ***It is possible, however, that other pharmacy benefits managers or third-party payors will follow ESI's action with similar actions of their own and that the actual impact on our business will differ, perhaps significantly, from our preliminary assessment.***
>
> [Emphasis added.]

181. While Defendants made these Item 303 disclosures, nowhere in the Form 10-Q, in the MD&A analysis or anywhere else, did Galena disclose: (1) Galena's net sales and revenues were the result of Galena's illegal promotion of Abstral for off-label purposes (*i.e.,* non-cancer pain) and

[8] Form 10-Q, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" instructs filers to "[f]urnish the information required by Item 303 of Regulation S-K (§ 229.303 of this chapter)."

illegal kickbacks paid to doctors that prescribed Abstral, including kickbacks for prescriptions that were known to be off-label; (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two pain doctor who made up 30% of all Abstral sales in the country and who were overprescribing Abstral for non-medical purposes in an attempt to manipulate Galena stock; and (3) that these trends, events and uncertainties were reasonably likely to have a material negative effect on Galena's results of operations. Accordingly, Defendants violated Item 303 of Regulation S-K. 17 C.F.R. § 229.303(a)(1) and (3) and (b). Given these circumstances and uncertainties, as Defendants knew, it was reasonably likely that Galena's Abstral sales could not be sustained and thus Galena's reported financial results were likely not indicative of future performance. The information that was required to be disclosed by Galena under Item 303 was material, and its omission misled investors to wrongly thinking that "no additional qualifying trends or uncertainties [under Item 303(a)] exist[ed]" and that "the quality of earnings and the likelihood that past performance [was] indicative of future performance." 54 Fed. Reg. at 22,428.

2. November 5, 2014 Form 10-Q Third Quarter 2014

182. On November 5, 2014, Galena filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendants Schwartz and Dunlap, and reaffirmed the Company's financial results announced in the press release issued the same day.

183. In the MD&A section (Item 2[9]) of the Form 10-Q, Galena disclosed:

> In March of 2014 we launched the Galena Patient Services (GPS) program, a full service support program designed to navigate patient access to Abstral that is coordinated through a third party vendor. Along with the launch of GPS, we also made changes to our patient assistance program (PAP) to reduce the use of free product vouchers and rely more heavily upon an expedited prior authorization process. These changes resulted in both a flattening in the growth in prescription demand and significant improvement in gross-to-net deductions, quarter-over-quarter

[9] Form 10-Q, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" instructs filers to "[f]urnish the information required by Item 303 of Regulation S-K (§ 229.303 of this chapter)."

> in 2014. ***We believe the slowed growth in quarter-over-quarter prescription demand is the temporary result of our GPS program and PAP rules changes, and we anticipate an increase in prescription demand and ex-manufacturer sales in the last quarter of 2014.***
>
> Our gross revenue is also affected by the timing of customer orders, which timing sometimes results in quarter-to-quarter fluctuations in gross revenue. From time to time we have offered favorable pricing and extended payment terms to new wholesale distributor customers as an incentive to place initial Abstral orders. ***In the second quarter of 2014, we afforded such incentives to one or our principal customers with respect to an order from which we recognized approximately $1.5 million of gross revenue (ex-manufacturer), or approximately $0.9 million of net revenue. The timing and amount of this significant order, and the timing of customer orders in general, may have contributed to a corresponding reduction in customer orders, and in related revenue, in the third quarter of 2014. We believe the same timing differences will create a recovery in net revenues in the fourth quarter,*** and expect for net revenue for the full year of 2014 to be within the range of our guidance of $8 million to $10 million through increased ex-manufacturer sales and a continued reduction in the gross to net deductions.
>
> [Emphasis added.]

184. While Defendants made these Item 303 disclosures, nowhere in the Form 10-Q, in the MD&A analysis or anywhere else, did Galena disclose: (1) Galena's net sales and revenues were the result of Galena's illegal promotion of Abstral for off-label purposes (*i.e.*, non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral, including kickbacks for prescriptions that were known to be off-label; (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two pain doctors who made up 30% of all Abstral sales in the country and who were overprescribing Abstral for non-medical purposes in an attempt to manipulate Galena stock; and (3) that these trends, events and uncertainties were reasonably likely to have a material negative effect on Galena's results of operations. Accordingly, Defendants violated Item 303 of Regulation S-K. 17 C.F.R. § 229.303(a)(1) and (3) and (b). Given these circumstances and uncertainties, as Defendants knew, it was reasonably likely that Galena's Abstral sales could not be sustained and thus Galena's reported financial results were likely not indicative of future performance. The information that was required to be disclosed by Galena under Item 303 was material, and its

omission misled investors to wrongly thinking that "no additional qualifying trends or uncertainties [under Item 303(a)] exist[ed]" and that "the quality of earnings and the likelihood that past performance [was] indicative of future performance." 54 Fed. Reg. at 22,428.

3. March 5, 2015 Form 10-K Year Ended December 31, 2014

185. On March 5, 2015, Galena filed its annual report on form 10- K with the SEC. The 10-K was signed by Defendants Schwartz and Dunlap, and reaffirmed the Company's financial results announced in the press release issued on the same day.

186. In the MD&A section (Item 7)[10] of the Form 10-K Galena disclosed:

> Abstral is our first commercial product and revenue was recorded for the first time during the year ended December 31, 2013. ***We acquired our second commercial product, Zuplenz, in the third quarter of 2014 and are expected to launch the product in the second quarter of 2015. There was no gross or net revenue from the sale of Zuplenz in 2014. For this reason, we expect our future results of operations to differ materially from our historical results. …***
>
> ***Further analysis of the changes and trends in our operating results are discussed below.*** [Analyzing changes and trends in operating results]
>
> [Emphasis added.]

187. While Defendants made these Item 303 disclosures, nowhere in the Form 10-K, in the MD&A analysis or anywhere else, did Galena disclose: (1) Galena's net sales and revenues were the result of Galena's illegal promotion of Abstral for off-label purposes (*i.e.*, non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral, including kickbacks for prescriptions that were known to be off-label; (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two pain doctors who made up 30% of all Abstral sales in the country and who were overprescribing Abstral for non-medical purposes in an attempt to manipulate Galena stock; and (3)

[10] Form 10-K, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" instructs filers to "[f]urnish the information required by Item 303 of Regulation S-K (§ 229.303 of this chapter)."

that these trends, events and uncertainties were reasonably likely to have a material negative effect on Galena's results of operations. Accordingly, Defendants violated Item 303 of Regulation S-K. 17 C.F.R. § 229.303(a)(1) and (3) and (b). Given these circumstances and uncertainties, as Defendants knew, it was reasonably likely that Galena's Abstral sales could not be sustained and thus Galena's reported financial results were likely not indicative of future performance. The information that was required to be disclosed by Galena under Item 303 was material, and its omission misled investors to wrongly thinking that "no additional qualifying trends or uncertainties [under Item 303(a)] exist[ed]" and that "the quality of earnings and the likelihood that past performance [was] indicative of future performance." 54 Fed. Reg. at 22,428.

4. May 7, 2015 Form 10-Q First Quarter 2015

188. On May 7, 2015, Galena filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendants Schwartz and Dunlap, and reaffirmed the Company's financial results announced in the press release issued on the same day.

189. In the MD&A section (Item 2) [11] of the Form 10-Q Galena disclosed:

> Abstral is our first commercial product and revenue was recorded for the first time during the year ended December 31, 2013. ***We acquired our second commercial product, Zuplenz, in the third quarter of 2014 and are expected to launch the product in the second quarter of 2015. There was no gross or net revenue from the sale of Zuplenz in the first quarter of 2015 or in 2014. For these reasons, we expect our future results of operations may differ materially from our historical results.*** … ***Further analysis of the changes and trends in our operating results are discussed below.*** [Analyzing changes and trends in operating results]
>
> [Emphasis added.]

190. While Defendants made these Item 303 disclosures, nowhere in the Form 10-Q, in the MD&A analysis or anywhere else, did Galena disclose: (1) Galena's net sales and revenues were the

[11] Form 10-Q, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" instructs filers to "[f]urnish the information required by Item 303 of Regulation S-K (§ 229.303 of this chapter)."

result of Galena's illegal promotion of Abstral for off-label purposes (*i.e.,* non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral, including kickbacks for prescriptions that were known to be off-label; (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two pain doctors who made up 30% of all Abstral sales in the country and who were overprescribing Abstral for non-medical purposes in an attempt to manipulate Galena stock; and (3) that these trends, events and uncertainties were reasonably likely to have a material negative effect on Galena's results of operations. Accordingly, Defendants violated Item 303 of Regulation S-K. 17 C.F.R. § 229.303(a)(1) and (3) and (b). Given these circumstances and uncertainties, as Defendants knew, it was reasonably likely that Galena's Abstral sales could not be sustained and thus Galena's reported financial results were likely not indicative of future performance. The information that was required to be disclosed by Galena under Item 303 was material, and its omission misled investors to wrongly thinking that "no additional qualifying trends or uncertainties [under Item 303(a)] exist[ed]" and that "the quality of earnings and the likelihood that past performance [was] indicative of future performance." 54 Fed. Reg. at 22,428.

5. August 6, 2015 Form 10-Q Second Quarter 2015

191. On August 6, 2015, Galena filed its quarterly report on Form 10-Q with the SEC. The 10-Q was signed by Defendants Schwartz and Dunlap, and reaffirmed the Company's financial results announced in the press release issued on the same day.

192. In the MD&A section (Item 2[12]) of the Form 10-Q Galena disclosed:

> Abstral is our first commercial product and revenue was recorded for the first time during the year ended December 31, 2013. ***We acquired our second commercial product, Zuplenz, in the third quarter of 2014 and launched the product in July 2015. There was no gross or net revenue from the sale of Zuplenz in any of the periods presented. For these reasons, we expect our future results of operations***

[12] Form 10-Q, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" instructs filers to "[f]urnish the information required by Item 303 of Regulation S-K (§ 229.303 of this chapter)."

> ***may differ materially from our historical results.*** … ***Further analysis of the changes and trends in our operating results are discussed below.*** [Analyzing changes and trends in operating results]
>
> [Emphasis added.]

193. While Defendants made these Item 303 disclosures, nowhere in the Form 10-Q, in the MD&A analysis or anywhere else, did Galena disclose: (1) Galena's net sales and revenues were the result of Galena's illegal promotion of Abstral for off-label purposes (*i.e.*, non-cancer pain) and illegal kickbacks paid to doctors that prescribed Abstral, including kickbacks for prescriptions that were known to be off-label; (2) Galena's net sales and revenues were reliant on illegal prescriptions of Abstral by two pain doctors who made up 30% of all Abstral sales in the country and who were overprescribing Abstral for non-medical purposes in an attempt to manipulate Galena stock; (3) that ***these two pain doctors' practices, clinics, and pharmacy had been shut down in May 2015***; and (4) that these trends, events and uncertainties—particularly the abrupt loss of 30% of the Abstral business—were reasonably likely to have a material negative effect on Galena's results of operations. Accordingly, Defendants violated Item 303 of Regulation S-K. 17 C.F.R. § 229.303(a)(1) and (3) and (b). Given these circumstances and uncertainties, as Defendants knew, it was reasonably likely (indeed all but certain) that Galena's Abstral sales could not be sustained, and thus Galena's reported financial results were not indicative of future performance. The information that was required to be disclosed by Galena under Item 303 was material, and its omission misled investors to wrongly think that "no additional qualifying trends or uncertainties [under Item 303(a)] exist[ed]" and that "the quality of earnings and the likelihood that past performance [was] indicative of future performance." 54 Fed. Reg. at 22,428.

194. In summation, by failing to disclose these material trends, events and circumstances, which investors expected to be disclosed in Galena's SEC Forms 10-K and 10-Q, Defendants misled investors. Defendants' disclosures when read in context implied that "no additional qualifying trends

or uncertainties [under Item 303(a)] exist[ed]," when they in fact did exist and were highly material. Importantly, Defendants' omissions materially misled investors about "the quality of earnings and the likelihood that past performance [was] indicative of future performance." 54 Fed. Reg. at 22,428.

D. Disclosures at the End of the Class Period

195. Marking the close of the Class Period, on January 31, 2017, the Company announced the resignation of Schwartz as President, CEO, and a member of the Board of Directors, stating:

> SAN RAMON, Calif., Jan. 31, 2017 (GLOBE NEWSWIRE) – Galena Biopharma, Inc. (NASDAQ:GALE), a biopharmaceutical company committed to the development and commercialization of hematology and oncology therapeutics that address unmet medical needs, today announced that the Board of Directors has entered into a separation agreement with Mark W. Schwartz, Ph.D. under which Dr. Schwartz will resign from the company and its affiliates as the President, Chief Executive Officer, and member of the Board of Directors, effective today. The Board of Directors expects to appoint an Interim Chief Executive Officer in the next couple weeks.
>
> The Board of Directors also announced that it is in the process of engaging an independent advisory firm to evaluate strategic alternatives for the company focused on maximizing stockholder value. Potential strategic alternatives that may be explored or evaluated as part of this review include continuing to advance the clinical programs as a stand-alone entity, a sale of the company, a business combination, merger or reverse merger, and a license or other disposition of corporate assets of the company. There is no set timetable for this process and there can be no assurance that this process will result in a transaction. While the Company evaluates its strategic alternatives, Galena's investigator-sponsored immunotherapy trials will remain ongoing. The Company is evaluating the appropriate time to commence the GALE-401 trial and anticipates making a definitive determination in the second half of 2017.
>
> "After critical assessment of the current status of the company, we believe that it is the right time to run a strategic evaluation of our opportunities as we look to maximize value for our stockholders," said Sanford J. Hillsberg, Galena's Chairman of the Board of Directors. "We acknowledge Mark's six years of service with Galena and wish him well in his future endeavors."

196. On the same day, January 31, 2017, *TheStreet.com* published an article on Schwartz' resignation. The article titled, "*Galena Sacks CEO Amid Escalating Criminal Probe Into Fentanyl Drug Marketing*," stated, "[t]he timing of Schwartz' exit is noteworthy given Galena's admission on Jan. 9 of a criminal investigation of the company by the U.S. Attorney's Office in New Jersey and the U.S. Department of Justice." As the article explained: "The Feds are investigating Galena's

marketing and promotional practices for Abstral, the company's fentanyl-based painkiller, according to an 8-K filing with the Securities and Exchange Commission. ***Schwartz was instrumental in Galena acquiring Abstral in 2013 and played a significant role in the drug's marketing***, according to former employees."

197. Other business and financial writers similarly associated Schwartz's resignation with the pending criminal investigation of Galena and the pending criminal proceeding against Drs. Ruan and Couch. For example, the *San Francisco Business Times* published an article on February 1, 2017 entitled, "Biopharma CEO Exits As Pain Drug Marketing Probe Deepens," which stated that "Galena Biopharma Inc. CEO Mark Schwartz abruptly left his post Tuesday, the company said, as a U.S. Justice Department investigation continues into the marketing of a powerful painkiller drug and the company ponders its future." The article went on to explain: "Federal investigators from the U.S. Attorney's Office in New Jersey and the Department of Justice have been investigating alleged 'pill mills' that prescribe painkillers and have fueled a national painkiller addiction epidemic. Abstral was among drugs prescribed by John Patrick Couch and Xiulus Ruan, co-owners of Physicians' Pain Specialists of Alabama, who have been charged by federal prosecutors with fraud."

198. On this news, the price of Galena common stock fell $0.37 per share, or 22.4%, to close at $1.28 per share on February 1, 2017. The stock price continued to decline, falling another $0.16 per share, or 12.5%, to close at $1.12 on February 2, 2017.

199. On May 26, 2017, Dr. Ruan and Dr. Couch were sentenced to 252 months and 240 months, respectively.

E. Motive

200. Throughout the Class Period, Defendants used Galena's artificially inflated stock to finance its operations. The Company was dependent upon financing to supplement revenues from its only salable product, Abstral. As Galena disclosed in its SEC filings, "[i]n the absence of revenue

from the commercialization of Abstral, Zuplenz or our product candidates, our potential sources of operational funding are proceeds from the sale of equity and funded research and development payments and payments received under partnership and collaborative agreements."

201. Thus, on November 18, 2014, the Company entered into a purchase agreement with Lincoln Park Capital, LLC ("LPC") that gave the Company the right to sell to LPC up to $50 million in shares of the Company's common stock over the 36 month term of the purchase agreement. LPC initially purchased 2.5 million shares of Galena common stock. As a result of this initial issuance, the Company received initial net proceeds of $4.9 million. In addition to the LPC's initial purchase of common stock, during 2014, Galena received net proceeds of $8.5 million from LPC's subsequent purchases of a total of 4.6 million shares.

202. During each of the years ended December 31, 2014 and December 31, 2015, respectively, the Company received $2.3 million in net proceeds from the sale of 1.4 million shares of common stock through At Market Issuance Sales Agreements.

203. In March 2015, the Company sold units consisting of common stock and warrants at $1.56 per unit for proceeds of $40.8 million.

204. Each of these financings were possible through, and facilitated by, the artificially inflated stock price. Had Abstral revenues not been inflated through Defendants' undisclosed illegal promotions of Abstral for off-label purposes, through Galena's illegal kickbacks to prescribers, and through the over-prescription of Abstral by at least two doctors (three doctors, including Dr. Rho) who were prescribing for off-label non-medical purposes in an attempt to receive kickbacks and manipulate Galena stock, the above financings would not have been available. Thus, Defendants were motivated to commit the fraud alleged herein in order to keep the Company's operations ongoing while its product candidates were in clinical development.

VI. CLASS ACTION ALLEGATIONS

205. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that acquired Galena's securities from August 11, 2014 through January 31, 2017, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

206. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Galena's common stock actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least hundreds or thousands of members in the proposed Class. Millions of Galena shares were traded publicly during the Class Period on the NASDAQ. As of October 31, 2016, Galena had 217,019,065 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Galena or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

207. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

208. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

209. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Galena; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

210. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

VII. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

211. The market for Galena's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Galena's securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Galena's securities and market information relating to Galena, and have been damaged thereby.

212. During the Class Period, the artificial inflation of Galena's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint, resulting in the

damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Galena's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Galena and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company stock. Defendants' materially false and/or misleading statements during the Class Period caused Plaintiffs and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

213. At all relevant times, the market for Galena's securities was an efficient market for the following reasons, among others:

(a) Galena stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Galena filed periodic public reports with the SEC and/or the NASDAQ;

(c) Galena regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Galena was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

214. As a result of the foregoing, the market for Galena's securities promptly digested current information regarding Galena from all publicly available sources and reflected such information in Galena's stock price. Under these circumstances, all purchasers of Galena's securities during the Class Period suffered similar injury through their purchase of Galena's securities at artificially inflated prices and a presumption of reliance applies.

VIII. NO SAFE HARBOR

215. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Galena who knew that the statement was false when made.

IX. FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

216. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

217. During the Class Period, Defendants made materially false or misleading statements in the Company's quarterly and annual reports filed with the SEC on Forms 10-Q and 10-K, in other documents filed with the SEC, and in the Company's press releases and/or in the Company's conference calls. Defendants misrepresented material facts or failed to disclose material facts required in order to make the statements they made not materially misleading.

218. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Galena's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Galena and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

219. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's

dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

220. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Galena's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

221. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Galena's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Galena's securities during the Class Period at artificially high prices and were damaged thereby.

222. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other

members of the Class and the marketplace known the truth regarding the problems that Galena was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Galena securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

223. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

224. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

X. SECOND CLAIM

Violation of Section 20(a) of The Exchange Act
Against Defendants Ahn, Schwartz, and Dunlap

225. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

226. Defendants Ahn, Schwartz, and Dunlap acted as controlling persons of Galena within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Defendants Ahn, Schwartz, and Dunlap had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Defendants Ahn, Schwartz, and Dunlap were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these

statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

227. In particular, Defendants Ahn, Schwartz, and Dunlap had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

228. As set forth above, Galena and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Defendants Ahn, Schwartz, and Dunlap are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

XII. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: September 20, 2018

Respectfully submitted,

/s/ William B. Federman

William B. Federman
(admitted *pro hac vice*)
FEDERMAN & SHERWOOD
10205 N. Pennsylvania Avenue
Oklahoma City, OK 73120
Telephone: (405) 234-1560
wbf@federmanlaw.com

Lead Counsel for the Class

Gary S. Graifman, Esq.
KANTROWITZ, GOLDHAMER & GRAIFMAN, P.C.
210 Summit Avenue
Montvale, New Jersey 07645
Telephone: (201) 391-7000

Liaison Counsel for the Class

CERTIFICATE OF SERVICE

This is to certify that on September 20, 2018, I electronically transmitted this document to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to the counsel of record.

/s/ William B. Federman

William B. Federman